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PROPOSAL

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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on monitoring and controlling drug precursors and repealing Regulations (EC) No 273/2004 and (EC) No 111/2005

Delegations will find attached document COM(2025) 747 final.

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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

{SEC(2025) 328 final} - {SWD(2025) 397 final} - {SWD(2025) 398 final} - {SWD(2025) 399 final}

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Recent years have witnessed a rise in drug-related violence and criminal activity amongst EU Member States, with illicit drugs like cocaine, heroin, opioids, and amphetamine-type stimulants (ATS) posing serious health and security problems. Moreover, the drug market is increasingly marked by the widespread availability of a broader range of drugs, often with higher potency or purity, and in new forms[(1)], aided by drug precursors. Drug precursors are chemicals necessary for the illicit production of drugs. However, they can also have significant legitimate use.

In recognition of the need to maintain controls to prevent the diversion of drug precursors towards illicit trade, the UN Convention against Illicit Traffic in Narcotic Drugs[(2)] obliges its Parties to take measures to prevent the diversion of substances frequently used in the illicit manufacture of drugs.

The Union concluded the UN Convention in 1990[(3)], and subsequently adopted rules on drug precursors. Currently, the UN Convention is implemented by Regulation (EC) No 273/2004 ('the Internal Market Regulation')[(4)] on monitoring and controlling drug precursors for their possession and placing on the market, and Regulation (EC) No 111/2005 ('the External Trade Regulation')[(5)] , for their trade between the Union and third countries.

These two regulations classify drug precursors as either scheduled (listed and controlled in the regulations) or non-scheduled (for which there are no legally binding obligations). Scheduled drug precursors are classified into several categories[(6)] depending on their role in illicit drug production and the existing legitimate trade, and thus varying degrees of controls. In addition, in 2013 the provisions granting powers to competent authorities were clarified regarding the possibility to take national measures to control suspicious transactions of non-scheduled drug precursors.

However, the situation has evolved since the adoption of these two regulations, with the rapid increase in designer precursors – drug precursors without any known legitimate use, except

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(1) EUDA, The European Drug Report 2025: Understanding Europe's drug situation in 2025 – key developments (European Drug Report 2025) | www.euda.europa.eu.

(2) The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, adopted in Vienna on 19 December 1988.

(3) Council Decision (90/611/EEC) of 22 October 1990 concerning the conclusion, on behalf of the European Economic Community, of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, OJ L 326, 24.11.1990, p. 56.

(4) Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1), ELI: http://data.europa.eu/eli/reg/2004/273/oj).

(5) Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 22, 26.1.2005, p. 1, ELI: http://data.europa.eu/eli/reg/2005/111/oj).

(6) Category 1 substances are the most critical, comprising chemicals that form the essential core molecules of drugs, making it impossible to produce these drugs without them. Category 2 covers less sensitive substances compared to Category 1. For internal trade, Category 2 is divided into categories 2A and 2B due to a higher risk of diversion of category 2A substances. Category 3 contains bulk chemicals which are significant in the illicit drug production but also have widespread legitimate uses. For external trade, Category 4 includes medicinal products that contain ephedrine and pseudoephedrine.

research and innovation. Equally, the obligations[7] set out in the regulations create administrative burden across the four categories of scheduled substances. Enforcement measures need to be strengthened in order to ensure the uniform implementation of rules across the EU.

From a security perspective, the proliferation and trafficking of designer precursors present significant challenges to drug precursor control at global level. In response, both the United Nations Commission of Narcotic Drugs (CND)[8] and the International Narcotics Control Board in its 2024 report recommend controlling chemicals that are closely related to controlled precursors – such as families or derivatives of controlled precursors.

In alignment with this strategy, countries like the USA, Canada, Argentina, Mexico and recently China introduced extended scheduling to families or derivatives of controlled precursors. This proactive approach is being followed at multilateral level through the CND[9]. Drug precursor controls are a crucial component of drug supply reduction policy as outlined in the EU Drugs Strategy 2021-2025[10] . The EU Drugs Action Plan 2021-2025[11] further highlights the need to address the challenge posed by designer precursors. Additionally, the 2023 EU Roadmap to fight drug trafficking and organised crime[12] stresses the need to set out innovative ways to speed up and broaden the current approach to regulating drug precursors in response to new methods of illicit drug production.

Protect EU: a European Internal Security Strategy[13] announced a new EU Drugs Strategy and an EU Action Plan against drug trafficking to disrupt routes and business models. The 2025 Commission Work Programme, under its security heading, announced the proposal of new rules governing drug precursors[14].

Drug precursors are chemicals with an essential role in industries such as pharmaceuticals, flavouring and fragrance, batteries, cosmetics, textiles, oil refinery, water treatment, food additives, explosives, rubber production, fertilisers, plastics or dyes.[15] Within the EU, there were approximately 4 000 active licenses or registrations to trade in drug precursors in 2023[16]. 92 % of these companies are small and medium-sized enterprises (SME)[17].

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(7) Depending on the category, operators and users must either hold a license or registration, secure their premises, report suspicious transactions, ensure proper labelling and documentation, maintain transaction records for three years, designate a responsible officer, obtain import and export authorisations, including pre-export notification, and limit trade to customers which have a licence or a registration.

(8) CND Resolution 65/3 ‘Intensifying efforts to address the diversion of non-scheduled chemicals frequently used in the illicit manufacture of drugs and the proliferation of designer precursors’ agreed in March 2022.

(9) At the March 2024 Commission on Narcotic Drugs, the INCB recommended scheduling as a direct application of UN Resolution 65/3, introducing proactive scheduling at the UN level.

(10) Council Conclusions on the EU Drugs Strategy 2021-2025, 14178/20, 18 December 2020.

(11) COM (2020) 606 final

(12) COM (2023) 641 final

(13) COM (2025) 148 final

(14) COM (2025) 45 final

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

(16) Namely, economic operators holding at least one active licence or registration for the EU market of drug precursors. Note that, as a proxy, this underestimates the figure since – at present – economic operators trading in Category 3 internally only, are not required to register and those trading in Category 4 are not required to register.

Supply chains for these chemicals involve a diverse range of actors, including large-scale chemical manufacturers who produce these substances in bulk for industrial use, as well as specialised producers who create more refined or custom chemical products tailored to specific industrial and research needs. Distributors and other logistics providers play key roles in ensuring that these substances are transported and stored safely. The Union chemical industry is a strategic sector, with 56 % of chemicals going to other sectors. It is therefore vital to simplify conditions to ensure that the legitimate industry is able to fully reap the benefits of the Single Market.

The proposal thus aims to address the challenge of preventing the use of drug precursors in the illicit manufacture of drugs, whilst simplifying rules and procedures for legitimate trade. More specifically, the introduction of specific rules on designer precursors and innovative means for their inclusion will allow quicker action to prevent their diversion. Through digitalisation, several obligations could be automated, leading to a significant reduction in the costs and the administrative burden for operators and the Member State national authorities.

The proposal would contribute towards the objectives set out in political guidelines of the Commission for 2024-2029, which announce the facilitation of business operations, particularly for SMEs[18], and aim to deepen the Single Market. The Competitiveness Compass emphasizes simplification as a key factor in boosting industry competitiveness.[19]

- **Consistency with existing policy provisions in the policy area**

The merging of currently separate instruments for EU internal and external trade will enhance legal clarity and consistency:

- The obligations under the two regulations have been simplified or automated, in line with the digital agenda. This will help reduce the administrative burden for operators and Member State authorities. In addition, a new category has been introduced for designer precursors.
- The inclusion of special rules for designer precursors in the proposal allows for the more effective monitoring and prevention of the proliferation of drug precursors towards illicit aims. Streamlined administrative procedures and a central electronic system will enable greater simplification and reduce overall burden for authorities and business alike, offsetting enforcement and due diligence costs, thereby resulting in a net cost saving. In addition, the drug precursors information repository will provide the necessary guidance to stakeholders.
- Merging the two existing regulations will enable the application of the same rules for internal and external trade, wherever possible.

- **Consistency with other Union policies**

The proposal is consistent with other Union policies and legislation, namely:

- Regarding illicit drug trafficking, the drug precursors regulations help determine the material scope of minimum national rules on criminal acts concerning precursors set out by Member States in accordance with Council Framework Decision

(17) There is no public source regarding share of SMEs trading in drug precursors. The percentage of the relevant (closest) manufacturing chemicals sub-sectors according to Eurostat data is 92%, which aligns with the view of public authorities consulted as part of the stakeholder consultations for this initiative.

(18) Ursula von der Leyen, Political Guidelines for the next European Commission 2024-2029, 18 July 2024, e6cd4328-673c-4e7a-8683-f63ffb2cf648_en (europa.eu).

(19) COM (2025)30 final

2004/757/JHA[20]. The EU Drugs Agency (EUDA) plays an important role with its new mandate[21] in the field of drug precursors, and the proposal duly acknowledges its expertise.

- The proposal does not interfere with other rules on chemicals such as the REACH Regulation[22] or the CLP Regulation[23], or other sectoral chemical legislation such as the Cosmetic Products Regulation[24] or the Detergents Regulation[25].
- Furthermore, with respect to customs policy, this initiative supports the EU Customs Reform[26] which aims to establish a new EU Customs Authority maintaining an EU Customs Data Hub. The Data Hub will replace the current fragmented customs IT infrastructure in EU Member States, enhancing interoperability with related policy areas. Data on drug precursors will be integrated into the Data Hub.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The proposal is based on Articles 33, 114 and 207 of the Treaty on the Functioning of the European Union.

• Subsidiarity (for non-exclusive competence)

The Union has shared competence in setting out rules on the control and monitoring of drug precursors within the internal market. The EU set out harmonisation rules on drug precursors since 1990. Two key arguments continue to justify EU action in this field. Firstly, illicit drug production is a Union-wide problem, not confined to a few Member States. EU action is needed to ensure that the efficiency of controls of drug precursors across the Union is not diminished by the existence of diverse national rules with various degrees of strictness, which would inadvertently lead to weaknesses. Secondly, Member States have the obligation to control and monitor transactions with drug precursors, in accordance with the UN Convention. Maintaining harmonised rules would ensure a smooth legitimate trade of chemicals in the single market. EU action would have clear benefits for businesses, national

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

(21) Regulation (EU) 2023/1322 of the European Parliament and of the Council of 27 June 2023 on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006

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

(23) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31/12/2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

(24) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22/12/2009, p. 59, ELI: http://data.europa.eu/eli/reg/2009/1223/oj).

(25) Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/648/oj).

(26) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the Union Customs Code and the European Union Customs Authority, and repealing Regulation (EU) No 952/2013, COM/2023/258 final, 2023/0156 (COD)

authorities and society as a whole, by empowering national authorities to better fight against illicit drug production, ensuring the good functioning of the internal market and reducing administrative burdens for economic operators and national authorities.

- **Proportionality**

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

- **Choice of the instrument**

The rules on controls and monitoring of drug precursors are to be set out in a Regulation, and thus directly applicable in all Member States. Drug precursors are often part of supply chains with operators in more than one Member State. The existence of uniform rules will ensure a level playing field among economic operators.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

The 2020 report from the Commission to the European Parliament and the Council on the evaluation of the EU drug precursor regulations [(27)] reveals a number of shortcomings that have emerged since the adoption of the Internal market and External Trade regulations, along with possible measures to address them. Notably:

- It underlines the need for action specifically targeting designer precursors. The current rules concern drug precursors where there is evidence of legitimate trade. Also, the current scheduling mechanism, based on a substance-by-substance approach, is too slow in keeping up with the fast pace of innovation by illicit drug manufacturers. There are hardly any limitations to the innovations of the producers of designer-precursors. In other words, each time a new substance is scheduled the criminals will be able to 'tweak some molecules' and come up with a new designer-precursor. The time needed for this can be short and in any case is often shorter than the period needed to schedule a new substance.
- Equally, the evaluation also underscores the administrative burden on operators and competent authorities, and the potential digitalisation offers in this regard, such as through e-licencing and the automatic validation through the European Union Single Window Environment for Customs[(28)]. Further examples of possible reduction of the administrative burden identified a facilitation of trade in low quantities of scheduled

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

(28) 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 (OJ L 317, 9.12.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/2399/2024-10-17).

drug precursors and the elimination of certain wait periods related to pre-export notifications for external trade.

- Moreover, consideration for the role of online marketplaces in the possible diversion and trafficking of drug precursors would help maintain the relevance of the regulations in the foreseeable future. In addition, the evaluation recommends strengthening the catch-all clause to allow more effective enforcement.

- **Stakeholder consultations**

The Commission carried out a number of consultation activities to collect evidence and views from a broad range of stakeholders on the problems identified with the Drug Precursors Regulations. Activities included (i) a twelve-week dedicated public consultation concluded in July 2024; (ii) two stakeholder workshops held on 14 November 2023 and 19 September 2024; (iii) discussions with Member States and other stakeholders in the Expert Group on Drug Precursors; and (iv) feedback collected in response to the Commission's Call for Evidence. As part of the impact assessment study, an external contractor also organised interviews with 78 relevant stakeholders, and two targeted surveys of national authorities and economic operators ran from 25 March to 17 May 2024 and 18 April to 14 June 2024 respectively. Consulted stakeholders included industry associations, economic operators, citizens, and national authorities. Most responses came from a business environment or from national authorities.

National authorities supported strengthening measures to prevent the diversion of drug precursors and, in particular, measures concerning the proliferation of designer precursors. They supported a moderate scope for a ban that would still enable legitimate activities such as research. They noted that this may lead to a higher implementation burden. Economic operators also supported measures in this field but stressed the need for a clear and univocal identification of banned substances (ideally through CAS number or other machine-readable coding) as a prerequisite to avoid undue increase of due diligence costs for legitimate trade. While the consultation activities gave mixed results on current administrative burdens, many stakeholders believed 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.

- **Collection and use of expertise**

Evidence supporting this initiative was gathered from existing documentary sources including legislation and other policy documents, customs and trade statistics, evaluations and reports on relevant policies and information on related initiatives, as listed in Annex 6 to the impact assessment.

- **Impact assessment**

The Commission carried out an impact assessment on the revision of the Drug Precursor Regulations. The Regulatory Scrutiny Board issued a positive opinion on the draft impact assessment on 6 June 2025. The impact assessment report was revised to take into account the Board's comments, in particular by better explaining how the uneven implementation and enforcement among Member States is a driving factor behind the problem; the extent to which the existing burdens pose a problem for economic operators and public authorities and why removing some measures would not increase the risks; why the two comprehensive review options are considered to be equally effective in reducing illicit trade and manufacturing; the evidence and methodology used to support the estimates of social impacts; and the key indicators to measure success.

The opinion of the Board as well as the final impact assessment and its executive summary are published together with this proposal. Based on the available information, the impact assessment examined and compared three policy options to address each of the two main problems identified. These policy options were in addition to the baseline option of no change, which would still allow for the inclusion of designer precursors in the scope of the current rules.

Policy option 1:

Policy option 1 aims at assessing the extent to which the current empowerments would be an effective and efficient means to meet the policy objectives of the initiative. The key measures of option 1 that would be underpinned by guidance and transparency measures involving the drug precursors information repository are the following:

• Specific rules for designer precursors in internal trade. Designer precursors rarely enter legitimate supply chains. Yet, their legitimate use in research and innovation, often in very small quantities, needs to remain possible. This is why for internal trade the obligations attached to designer precursors are rendered more targeted. Legitimate use is notified to the competent authority who may then investigate further.

• Simplify reporting obligations by switching from an ex-post to an ex-ante for internal trade: In line with the idea of maintaining high levels of control while streamlining the administrative requirements linked to the controls, this option also seeks to facilitate reporting for economic operators and authorities.

Policy option 2:

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

• Streamlining and reorganisation of the existing categories of substances: The new set of categories therefore aim to clarify and streamline obligations and controls based on an updated perception of the risk-profile of a group of substances.

• Introducing a new category for designer precursors with an a priori ban: Designer precursors are different from traditional designer precursors in that their legal use is often limited to research activities, but other future legitimate uses cannot be excluded a priori. Use or transactions of such precursors in small quantities for research and innovation should be subject to a prior notification to national authorities, while transactions and use in larger quantities is to be subject to a licence.

• Innovative and more forward-looking ways of scheduling: Option 2 would adapt the rules to the inclusion of groups of substances, for instance based on a chemical base molecule and a limited number of precise modifications to these base molecules.

Policy option 3:

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

• Streamlining existing categories of substances and increasing control measures applicable to them: While option 3 also entails a streamlining of categories, the focus is on increasing controls. The aim of extending controls is to have a better overview of legal trade in all precursor substances. This should enable authorities to monitor trade more closely.

• Introducing a new category for designer precursors with a greater focus on ex-ante controls by requiring special licences in all cases.

• Broader approach to innovative scheduling: Option 3 would imply including group of substances with base molecules (represented by their structural formula) and allow for an extended number of modifications to these, resulting in a larger number of substances to be scheduled.

Comparison of the options:

Option 1, while reducing time for scheduling and facilitating knowledge, was expected to fall short of expectations in terms of addressing the proliferation of designer precursors and related social impacts. It was considered to lead to limited burden reduction for internal trade only and have marginal environmental impacts.

Option 3 was expected to largely deliver the same results as Option 2. It was expected to maximise the reduction in the availability of precursors used in the manufacturing of illicit drugs. Given that it would be more costly to enforce due to the larger number of substances to be screened and higher control burdens on legitimate businesses, some Member States did not support excessively broad scheduling of substances as they may not be in the position to cope with the required effort.

Preferred policy option

Policy option 2 is the preferred option 2 as it was considered to be most effective against the proliferation of designer precursors and the trafficking of non-scheduled substances.

In terms of economic impacts, this option and especially the larger scope of substances scheduled as designer precursors is expected to come with an increase of about 10% in enforcement costs. Economic operators would face a one-off cost of about EUR M 7.7 for ensuring that newly scheduled designer precursors are not included in their portfolio. of the measures on designer precursors are offset by the streamlining and simplification of the regulatory framework. Yet, the development of an electronic system provides for the modernisation of the control system, alongside the provisions for digital verification of customers in the internal trade of Category 1 and Category 3 drug precursors. The burden of the EU control system for legal trade is reduced through the lifting/automation of various requirements. Overall, the streamlining and digitalisation of procedures is expected to lead to an administrative burden reduction of EUR M 25.27 per year. These changes should contribute to effectively facilitating trade and promoting the competitiveness of the sector.

For social impacts, the real-time reporting of significant seizures and urgency procedure will reduce significantly the time to detect and respond to new threats, while enabling authorities to target controls more specifically on those substances that are at a higher risk of being used in illegal drug production. Overall, this is expected to help reduce the availability of precursors used in the manufacturing of illicit drugs (especially synthetic drugs). Economic operators' awareness, and engagement will improve. Indirectly, the initiative should therefore reduce the availability of illicit drugs and may thus contribute to a reduction of social costs caused by illicit drug trafficking and consumption.

No direct environmental effects are expected but an overall reduction of illicit drug production may reduce illegal waste disposal from drug productions sites.

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

- **Regulatory fitness and simplification**

The initiative has a strong simplification dimension. Namely, through:

- A merger of the two regulations into a single regulation, aligning rules for both the internal market and external trade wherever possible.
- Fewer categories of scheduled drug precursors, from 4 to 3. Introducing a specific category for designer precursors provides greater clarity to operators and national authorities alike that such substances are subject to an outright ban. In addition, the initiative includes an exemption to this ban for small quantities for research and innovation. In case a legitimate use for a Category 3 drug precursor is discovered, the Commission and Member States will assess if such a substance should be placed in another category or exempt from the scope of the regulation.
- Due to the risk of diversion, the proposal does not exempt micro enterprises. However, where reasonable the proposal foresees exemptions for small quantities and for pharmacies and veterinary dispensaries.
- From a digital perspective, the development of a central electronic system allows for several improvements:
    - Digital applications for licences (new Categories 1 and 3) and registration for external trade (new Category 2).
    - Digital controls for imports and exports by the EU Single Window Environment for Customs and the lifting of the Pre-Export Notification (PEN) waiting period.
    - Reporting obligations are automated by aggregating the data entered into the central electronic system. The process of verifying customers will be digitalised.

The above should lead to reduced administrative costs for operators and public authorities. The benefits accruing from the consolidation of the two regulations are difficult to quantify since they relate to the time spent understanding the rules and how to comply with them (i.e. they are a complementary action for the compliance with the actual obligations themselves).

The initiative will reduce obligations for certain substances to better facilitate trade (such as in the removal of administrative costs related to the reporting requirement). It will also extend obligations to support enhanced control (i.e., due diligence costs for the implementation of the ban on designer precursors. Globally there will be a net reduction in costs, with the impact assessment estimating this net cost saving as amounting to approximately EUR 25,27 million per year.

- **Fundamental rights**

The proposal complies with the EU Charter of Fundamental Rights. The freedom to conduct business set out in the charter is not absolute. The restrictions set out in this proposal such as requesting a licence for performing activities involving Category 1 or Category 3 drug precursors are justified by the need to monitor activities with such precursors and reduce their availability for the illicit manufacture of drugs. This objective is in line with the general objective of providing a high level of human health protection in the definition and implementation of all the Union's policies.

4. BUDGETARY IMPLICATIONS

Member States and operators will rely on a centralised electronic system that will streamline and support the process for managing licences, registrations, customer verifications, quantity management, and prior notifications. The new rules will eventually remove the periodic reporting obligations for operators and authorities.

Comprehensive digital solutions are expected to facilitate the completion of administrative tasks for operators and to expedite the overall process. Moreover, it will enable competent authorities to verify the legality of drug precursors movements more effectively, improving traceability.

Digitalisation will enhance the effectiveness and efficiency of controls, providing authorities with faster access to structured, high-quality information that allows for automatic checks of licences/registrations and perform quantity management. This will support faster clearance times for imports and exports while strengthening the EU's ability to detect and prevent illicit trade.

- To achieve this, budgetary needs for the internal market IT system and human resources are estimated to amount to EUR M 1.322, starting from 2028.
- For external trade, a preliminary analysis led to a budget requirements estimation of up to EUR M 24.148, including human resources, depending on the IT solution delivery model chosen.
- An information repository of drug precursors which will cover all relevant scheduled and non-scheduled substances having or not a known industrial or commercial use which will, including human resources, cost approximately EUR 0.530 M.

Further information on these costs can be found in Section 3.2 of the Legislative Financial Digital Statement. The post-2027 figures are indicative, without pre-empting and pre-judging the Commission proposal and the agreement on the next MFF.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The Commission will evaluate the Regulation 10 years after its entry into application with a view to assessing its effectiveness, efficiency, relevance, added value and coherence. The Commission will submit a report on the main findings to the European Parliament and to the Council.

- **Detailed explanation of the specific provisions of the proposal**

Article 1 defines the subject matter of the Regulation, which is to set out rules for monitoring and controlling drug precursors both for activities in the internal market and for external trade.

Article 2 defines the most important notions used in the Regulation, using whenever possible cross-references from other related Union acts to ensure consistency.

Article 3 defines the material scope of the rules. Drug precursors are to be understood as referring to substances, mixtures, organisms and substances which occur in nature which can be used in the illicit production of drugs. While both scheduled and non-scheduled drug precursors are covered, there are specific conditions in which certain mixtures are excluded from the scope. In addition, the activities of public authorities, such as armed forces or police, acting within the scope of their official duties, as well as the use or possession of drug precursors by pharmacies and veterinary dispensaries are also excluded from the scope, due to the low risk of diversion. Furthermore, while making available on the market, use and

possession of medicinal products or veterinary medicinal products are excluded from the scope of the Regulation, external trade is covered only for those products included in Part II of Annex II to the Regulation.

Article 4 includes the standard free movement clause, which will ensure that Member States will not impede making available on the market scheduled drug precursors, if the requirements in the Regulation are fulfilled, by imposing additional monitoring measures, for instance.

Article 5 lists the 3 categories of scheduled drug precursors and sets out the conflict rules to be used to determine the requirements in specific cases where either a substance belongs to two categories, or a mixture contains substances belonging to two or three categories.

Articles 6 to 8 set out the general obligations applicable to operators trading with scheduled drug precursors. Operators have a general obligation of cooperation with national authorities and to keep documentation on their transactions with scheduled drug precursors. To support national authorities in fighting the illicit manufacture of drugs, operators and providers of online marketplaces have the obligation to notify suspicious transactions and significant disappearances or thefts of scheduled drug precursors.

Articles 9 to 14 lay down the requirements for placing on the market, use, possession, import, export or intermediary activities with Category 1 drug precursors. These are the drug precursors with legitimate uses in the chemical industry with the highest risk of diversion. Therefore, they are subject to strict control measures. In addition to the requirement to hold a licence, the operators have to designate a responsible officer, secure premises and trade in the internal market only with operators also holding a licence. Equally, operators using or possessing Category 1 drug precursors also have to keep the documentation, in similar conditions as those for operators trading with any scheduled drug precursor.

Article 15 lays down the requirements for import, export or intermediary activities with Category 2 drug precursors. External traders of Category 2 scheduled drug precursors will no longer need to apply for, and subsequently be granted, a registration for import, export, or intermediary activities. Instead, they will simply register information on their activities, including the estimates of maximum quantities envisaged during a validity period of three years, after which they can start activities involving the scheduled drug precursors they register. This information will be updated as required. Competent authorities may decide to suspend or cease the activities included in the registration in case the conditions declared are no longer fulfilled or in case of suspicion of risk of diversion towards illicit purposes.

Articles 16 to 19 set out the requirements for the newly introduced Category 3 drug precursors concerning designer precursors. Category 3 drug precursors contain substances which have no known legitimate use other than research or innovation at the moment of placing them under control. Therefore, the trade, use or possession of such substances should, *a priori*, be banned. Transactions, use or possession of small quantities for research and innovation should be allowed subject to a prior notification. If needed in larger quantities or for other legitimate uses, a licence is to be requested.

Articles 20 to 23 lay down procedures related to external trade in drug precursors. The new rules enable the simplification of external trade procedures through automation. Articles 20 and 22 set out the requirements for import and export authorisations, which are replaced by a system of quantity management, whereby the operator notifies the competent authority of the maximum quantity of scheduled substances to be imported or exported over a specific time period. This would also cover one or more intended import or export activities during this time up to a ceiling of the total quantity originally indicated. Article 23 sets out the provision

for customs verification, whereby the central electronic system will connect to the Single Window Environment for customs to verify the information provided on intended imports or exports against the operator's licence, registration, or prior notification details.

Article 21 sets out the process for pre-export notifications, which has been further streamlined. The pre-export notification obligation has been waived for countries in the European Economic Area (EEA). In addition, the 15-day wait period provided to third countries to reply to such a pre-export notification has been lifted.

Article 24 maintains the current provisions that external traders will continue to have the obligation to demonstrate the licit purpose when the scheduled drug precursors are transhipped, placed in temporary storage, or stored in a free zone.

Article 25 sets out a Drug Precursors Information Repository, which is to replace the existing Voluntary Monitoring List. The Repository is to contain information on the scheduled and non-scheduled drug precursors. It has several purposes: to support the operators in identifying suspicious transactions and in determining if specific substances are within the scope of the Regulation in case of including groups of substances identified in a generic way, and to support the Commission and national authorities in identifying the need to place new substances under control. The Repository is to be developed and maintained by the European Union Drugs Agency.

As additional measures to raise awareness and support Member States in the fight against the illicit manufacture of drugs, Article 26 sets out rules on training both for national authorities and operators.

Article 27 sets out provisions on mutual assistance between the Member States and between the Member States and the Commission, in particular by recourse to Council Regulation (EC) No 515/97[(29)].

Article 28 sets out an obligation for competent authorities to perform controls on the fulfilment of the obligations of this legislation with regard to scheduled drug precursors.

Articles 29 and 30 provide catch-all provisions for drug precursors. Competent authorities are empowered to intervene to avoid diversion towards the illicit production of drugs in the internal market by seizing scheduled drug precursors for a determined period of time in the conditions set out in the national law. For external trade, the powers of customs and competent authorities to monitor and control the possible diversion of both scheduled and non-scheduled precursors are strengthened by enabling Member State competent authorities with the tools to adopt stricter provisions for non-scheduled precursors, such as temporary detention, if they deem necessary. In addition, the requirement of strict control measures for all customs procedures is highlighted.

Article 31 sets out an obligation for Member States to adopt national rules on penalties, to ensure the enforcement of the Regulation.

Article 32 concerns the reporting of information on seizures by competent authorities and customs authorities, while Article 33 sets out specific information obligations for Member States which could lead to future developments as regards substances included in the categories of scheduled drug precursors or in the Repository, as non-scheduled drug precursor.

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(29) OJ L 82, 22.3.1997, p. 1. Regulation as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

Article 34 elaborates on the annual reporting obligation to the UN, to be performed by the Commission in consultation with Member States. The existing annual reporting obligations of operators are removed, as automation can provide this information. This allows the reporting obligations as per international obligations to continue with a more sustainable focus of resource utilisation.

Article 35 sets out the main functions of a centralised IT system for drug precursors which is to support the implementation of the various obligations. The system should allow operators to fulfil their obligations laid down in this Regulation and competent authorities, to make their decisions on the implementation of this Regulation and perform their reporting obligations. The system should also facilitate the communication by the Commission of information requested under the UN Convention. The centralised system is to be interconnected with the Single Windows Customs system, to enable the application of a quantity management system and thus replace the existing system of import and export authorisations. In addition, the system could be made compatible with the UN system for reporting of precursors incidents, so that the reporting of seizures in the electronic system is not a duplication of the existing reporting obligation under the UN Convention. The Commission is to adopt an implementing act setting out implementation arrangements for the electronic system, including the technical and the procedural requirements that stem from its functions.Article 36 covers the protection of personal data in the context of the operation of the electronic system.

Article 37 sets out the Commission empowerment for technical adaptations to the Annexes to amend the substances placed under control. In addition, the Commission is to amend other non-essential elements regarding, for instance, licences, registrations, prior notifications, quantity notifications for import or export, reporting obligations or transitional measures.

Article 38 describes the conditions for exercising the empowerment to adopt delegated acts.

Article 39 allows the Commission to use the urgency procedure to adopt delegated acts in duly justified cases, for changes to the controlled substances.

Article 40 ensures that the Commission will follow the examination procedure when adopting implementing acts regarding the implementation arrangements for the IT system.

Articles 41 to 45 refer to final and transitional arrangements. The Commission is to review the Regulation after a period of 10 years of application. This will allow the Commission to also consider the application of the quantity management system in the first evaluation of the Regulation, which is an essential element, and which is applicable only at a later stage when the IT system is fully developed. While Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 are to be repealed, transitional provisions are also proposed to ensure legal clarity as regards documents issued under the old rules. The application of the new rules should be deferred with 3 years to give the Commission time to develop part of the functions of the IT system to support its implementation and the operators and national authorities time to adapt. Since the other functions of the IT system supporting the quantity management for imports and exports will be operational at a later stage, a dedicated Annex sets out the transitional arrangements for the additional period as regards external trade and the reporting of external traders on their annual transactions.

2025/0384 (COD)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 33, 114 and 207 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure[2],

Whereas:

(1) The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988 ('the UN Convention') is part of the worldwide effort to combat the production and trafficking of illicit drugs. The Union concluded the UN Convention by means of Council Decision 90/611/EEC[3].

(2) Article 12 of the UN Convention requires the Parties thereto to take the measures they deem appropriate to prevent the diversion of substances which are included in the tables annexed to the Convention and used for the purpose of the illicit manufacture of drugs (drug precursors). The adoption of rules to monitor and control these drug precursors was implemented in the Union by Regulation (EC) No 273/2004 of the European Parliament and of the Council[4], regarding the control and monitoring measures within the internal market; and Council Regulation (EC) No 111/2005[5] on trade between the Union and third countries.

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(1) OJ C [...], [...], p. [...]

(2) Position of the European Parliament of [date] (not yet published in the Official Journal) and decision of the Council of [date].

(3) Council Decision of 22 October 1990 concerning the conclusion, on behalf of the European Economic Community, of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (OJ L 326, 24.11.1990, p. 56, ELI: http://data.europa.eu/eli/dec/1990/611/oj).

(4) Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, ELI: http://data.europa.eu/eli/reg/2004/273/oj).

(5) Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 22, 26.1.2005, ELI: http://data.europa.eu/eli/reg/2005/111/oj).

(3) The Evaluation of the Union drug precursor regulations[6] has shown that additional action with regard to designer precursors is necessary. Designer precursors are substances closely related to controlled drug precursors, with no known legitimate use, and which evade the controls set out in Regulations (EC) No 273/2004 and 111/2005. Those Regulations have been conceived to address the diversion of traditional drug precursors from licit channels towards the illicit manufacture of drugs, and do not include specific rules addressing designer precursors. The evaluation also pointed out to the need to take a holistic approach in regulating drug precursors, to ensure consistency with recent policy developments at Union level against drug trafficking. Recent developments include the EU Drugs Strategy and Action Plan, the adoption of Regulation (EU) 2023/1322[7] on the European Union Drugs Agency, the European Digital Strategy and the adoption of Regulation (EU) 2022/2399[8].

(4) Drug precursor controls are a crucial component of drug supply reduction policy as outlined in the EU Drugs Strategy 2021-2025[9]. Furthermore, the EU Drugs Action Plan 2021-2025[10] highlights the need to address the challenge posed by designer precursors. Additionally, the 2023 EU Roadmap to fight drug trafficking and organised crime[11] stresses the need to set out innovative ways to speed up and broaden the current approach to regulating drug precursors in response to new methods of illicit drug production. Equally, as part of the new EU Drugs Strategy and EU Action Plan against drug trafficking, announced in Protect EU: a European Internal Security Strategy[12], the EU will boost operational efforts to stop the inflow of drug precursors, including designer precursors. .

(5) Therefore, new rules on drug precursors should be adopted, to better address the developments in the illicit manufacture of drugs, and in particular, the proliferation of designer precursors. These new rules would also give effect to the obligations deriving from Article 12 of the UN Convention.

(6) In order to streamline current procedures and to reduce administrative burden, Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 should also be merged into one Regulation. That should also facilitate the free movement of chemicals in the internal market. This Regulation should apply without prejudice to other Union legislation applicable to the substances contained in drug precursors

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(6) Report from the Commission to the European Parliament and the Council of 30.11.2020 - Evaluation of the EU drug precursors regulations (COM/2020/768 final).

(7) Regulation (EU) 2023/1322 of the European Parliament and of the Council of 27 June 2023 on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006 (OJ L 166, 30.6.2023, p. 6., ELI: http://data.europa.eu/eli/reg/2023/1322/oj).

(8) 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 (OJ L 317, 9.12.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/2399/oj).

(9) Council Conclusions on the EU Drugs Strategy 2021-2025, 14178/20, 18 December 2020.

(10) Communication COM (2020) 606 final of 24.7.2020 from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - EU Agenda and Action Plan on Drugs 2021-2025.

(11) Communication COM (2023) 641 final of 18.10.2023 from the Commission to the European Parliament and the Council on the EU roadmap to fight drug trafficking and organised crime.

(12) Communication COM (2025) 148 final of 1.4.2025 from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on ProtectEU: a European Internal Security Strategy.

covered by this Regulation, such as Regulation (EC) No 1907/2006[14], Regulation (EC) No 1272/2008[15] or Regulation (EU) 2019/1148[16]. It should also apply without prejudice to the obligations of Member States to set out national rules on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking in accordance with Council Framework Decision 2004/757/JHA[17]. This Regulation should not apply to customs, police, armed forces and laboratories of competent authorities in the Member States when they are acting within the scope of their official duties, as the risk of diversion of drug precursors in such cases is minimal. The possession and use of drug precursors by pharmacies and veterinary dispensaries within the scope of their regular activities should also be exempt from the scope of the Regulation, as such operators are already subject to strict rules under Union and national legislation. The possibility of setting out simplified formalities for specific external traders, such as pharmacies and dispensaries of veterinary products, should be maintained to reduce the administrative burden for operators with a low risk profile.

(7) Scheduled drug precursors consist of or contain substances covered by the annexes to this Regulation. The annexes should include all the substances already covered by Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005. Such substances are either covered by the UN Convention or are placed under control at Union level, in response to specific risks of diversion identified in the Union. To facilitate their free movement in the internal market and their external trade, harmonised rules should be set out to enable national authorities to control and monitor legitimate trade effectively, with a view to avoiding their diversion towards the illicit manufacture of drugs, without creating disproportionate administrative burdens. As is the case under the current rules, operators should continue to have the obligation to notify suspicious transactions. This is an important source of information for competent authorities to discover illicit activities. The obligation should be extended to significant disappearances and thefts, as such incidents could also indicate possible diversion towards the illicit manufacture of drugs. Similarly, operators should maintain their obligation to keep the documentation regarding transactions of scheduled drug precursors. To increase the possibility for competent authorities to gather evidence concerning illicit activities, the obligation to keep documentation should be extended to operators using scheduled drug precursors of the highest risk and the documentation should be kept for a longer period of time.

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(14) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

(15) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

(16) Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013 (OJ L 186, 11.7.2019,ELI: http://data.europa.eu/eli/reg/2019/1148/oj).

(17) Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335, 11.11.2004, p. 8, ELI: http://data.europa.eu/eli/dec_framw/2004/757/oj).

(8) This Regulation should lay down specific obligations for online marketplaces with respect to reporting suspicious transactions with scheduled drug precursors that take place on their websites or that use their computing services, once they have become aware of information leading to such a suspicion. The obligations on online marketplaces under this Regulation should not amount to a general monitoring obligation.

(9) Category 1 drug precursors should be subject to strict control rules as they contain substances playing a key role in the illicit manufacture of drugs, but also with important legitimate uses which increases the risk of diversion from licit channels. Operators making available on the market, importing, exporting, performing intermediary activities, possessing or using such drug precursors should continue to be required to hold a licence, as this offers national authorities the possibility to make a thorough check of their legitimate intentions before the activity can be performed. Where fees are levied at national level for obtaining a licence, Member States should adjust such fees in order to safeguard the competitiveness of small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC[18]. The existing obligation of operators to verify that their customers also hold a licence should be maintained, as it proved to be an efficient way of verifying the reliability of such customers. However, the obligation to obtain customer declarations should no longer be maintained, as it leads to administrative burden without clear benefits in terms of facilitating the identification of suspicious transactions. It is also important to maintain the existing obligation of operators trading in Category 1 drug precursors to secure premises, and to extend it to operators using such drug precursors, given their high risk of diversion.

(10) Category 2 drug precursors are precursors which, even though frequently used in the illicit production of drugs, are traded in significant quantities in the internal market and external trade and have extensive legitimate uses. While the risk of diversion is significant, strict control measures would be very cumbersome both for the industry and for the national authorities, with limited added value for the identification of suspicious activities. Therefore, the control and monitoring measures under this Regulation should be focused only on the external trade. To reduce the administrative burden, obligations for external traders should be limited to registering their activities, without the requirement of approval by national authorities.

(11) Category 3 drug precursors should be introduced to address the particularities and high risks for use in illicit drug production associated with designer precursors, which play a significant role in the illicit manufacture of drugs, as demonstrated by their high proportion in the number of seizures in the recent years, and do not have any known legitimate use other than research and innovation. Such precursors do not follow the traditional pattern of diversion from licit channels towards the illicit manufacture of drugs. In support of the fight against the production and trafficking of illicit drugs, it is therefore important to ban them from: being made available on the market; import; export; intermediary activities; and their use or possession.

(12) However, as Category 3 drug precursors can be used in research and innovation and other legitimate uses may be discovered after the inclusion of various substances in the

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[18] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, C(2003) 1422 (OJ L 124, 20.5.2003, pp. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).

annex to this Regulation, it is important to set out rules allowing operators to perform activities with such precursors. Should small quantities of designer precursors be needed for research and innovation, operators should be required to file a prior notification to the competent authority in the Member State where they are established. That will encourage research and innovation by not imposing costly and lengthy formalities for transactions of low quantities and therefore low risk. Should operators need Category 3 drug precursors in higher quantities or for legitimate purposes other than research and innovation, they should then be required to obtain a licence in accordance with the provisions for Category 1 drug precursors, as the risks are similar.

(13) As new designer precursors can be easily created by modifying the chemical structure of substances placed under control, it is important that this Regulation is adapted to cater for the introduction of both a list of substances identified individually and of groups of substances identified in a generic way in Category 3 drug precursors. Whenever a group of substances is included in a generic way, an exemption list should be provided to exclude individual substances that are part of this group but for which a legitimate use other than research and innovation has been identified and which are not included in either Category 1 or Category 2 drug precursors.

(14) The requirement for obtaining import and export authorisations should be removed and replaced by quantity management, comprising quantity notification by operators and automatic verifications by customs authorities for import and export. That should reduce the administrative burden for external traders, whilst at the same time maintaining strict controls of drug precursors entering or leaving the customs territory of the Union and ensuring continued fulfilment of the UN Convention by the Union and its Members States.

(15) In accordance with Article 12(10) of the UN Convention, the effectiveness and practicability of pre-export notifications is fully recognised. However, exports to non-Member States participating in the Union Single Market and exports to countries where an international agreement waives the pre-export notification, should be exempt from the pre-export notification obligation.

(16) To enforce this Regulation effectively, it is important to enable competent authorities to request proof of licit purposes for drug precursors entering the customs territory of the Union.

(17) It is essential to step up efforts for raising the awareness of legitimate operators to the risks associated with non-scheduled precursors, to support them in identifying suspicious transactions and notifying them on voluntary basis. Thus, extensive information on drug precursors, including non-scheduled ones, and a tool to help determine the scope of scheduled designer precursors, will be made available through a Drug Precursors Information Repository.

(18) The Drug Precursors Information Repository should be developed, maintained, and kept up to date by the European Union Drugs Agency and should replace the existing Voluntary Monitoring List. The Repository should contain comprehensive information on scheduled and non-scheduled drug precursors, and their legitimate and illicit uses, to support operators in identifying suspicious transactions and Member States and the Commission in identifying new trends in the illicit production of drugs.

(19) Member States should organise regular training to raise awareness on the risks of diversion of drug precursors and the significant role which operators can play in the fight against the illicit manufacture of drugs.

(20) Mutual assistance between Member States and between Member States and the Commission should be reinforced, in particular by recourse to Council Regulation (EC) No 515/97[19].

(21) To prevent the diversion of drug precursors towards the illicit manufacturing of drugs, national authorities and customs authorities should be empowered to seize and confiscate both scheduled and non-scheduled drug precursors, if there are reasonable grounds or evidence that the drug precursor is intended for illicit use.

(22) To ensure the correct application of this Regulation, Member States should lay down rules on penalties applicable for infringement of this Regulation, which should be effective, dissuasive and proportionate.

(23) The annual reporting obligation for operators should be removed, as it has not been proven to be the most efficient measure in the identification of suspicious activities, while being very burdensome for the industry. Instead, the efforts of national authorities should be increased in reporting, without delay, significant seizures of drug precursors. This would ensure that national authorities from other Member States can better target their controls.

(24) Following the Union's obligations of reporting in Article 12(12) of the UN Convention and Resolutions of the United Nations Economic and Social Council 1995/20 on measures to strengthen international cooperation to prevent diversion of substances included in table I of the UN Convention and used in the illicit manufacture of stimulants and other psychotropic substances and 49/3 strengthening systems for the control of precursor chemicals used in the manufacture of synthetic drugs, the Commission should draw up an annual report to be sent to the International Narcotics Control Board.

(25) A centralised electronic system should be established to digitalise all the procedures set out in this Regulation. The system should allow operators to fulfil their obligations laid down in this Regulation and competent authorities to make their decisions on the implementation of this Regulation and perform their reporting obligations. The system should also facilitate the communication by the Commission of information requested under the UN Convention. The enforcement of drug precursors entering or leaving the Customs territory of the Union under this Regulation should be facilitated by the interconnection between that electronic system and the 'EU Single Window Environment for Customs'. In addition, the Commission should explore with the United Nations to possibly interconnect the electronic system with the United Nations system for the reporting of incidents with precursors or other tools, to avoid double reporting and facilitate the international cooperation. The Agency should have access to the information in the electronic system to facilitate the implementation of its mandate under Regulation (EU) 2023/1322 and the development and update of the Drug Precursors Information Repository.

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[19] Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters (OJ L 82, 22.3.1997, p. 1, ELI: http://data.europa.eu/eli/reg/1997/515/oj).

(26) Any processing of personal data under this Regulation should be carried out in compliance with the provisions of Regulation (EU) 2016/679[20] or Regulation (EU) 2018/1725[21] of the European Parliament and of the Council, within their respective scope of application.

(27) In order to amend certain non-essential elements of this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty of the Functioning of the European Union should be delegated to the Commission to add or remove substances from the categories of drug precursors, where necessary as a matter of urgency. Given the particularities of designer precursors which are close chemical relatives of scheduled drug precursors and can be easily created, the Commission should have the possibility to add designer precursors also by including groups of substances, identified in a generic way and, where needed, to exclude individual substances part of such groups which have legitimate uses other than research and innovation and which are not to be included in a different category. However, the Commission should not add groups of substances in Category 1 or Category 2 drug precursors, unless this is necessary to fulfil the obligations under the UN Convention. In addition, the Commission should be empowered to amend non-essential elements set out in the annexes concerning licences, registrations, prior notifications, quantity management related to import and export, pre-export notifications, demonstration of licit purposes, determining the criteria for suspicion on intention of use in the illicit manufacture of drugs, transitional measures and reporting. It is of particular importance that the Commission carry out appropriate consultations during the preparatory work for the adoption of delegated acts, including at expert level and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[22]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(28) Implementing powers should be conferred on the Commission in order to determine the implementing arrangements for the electronic system. These arrangements should include technical requirements and procedures for the implementation of the main obligations set out in this Regulation, such as obtaining a licence, filing a registration or prior-notification, or those linked to quantity notification and customs verification. These arrangements should also include the rules for the protection, safety and security of personal data. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1].

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(20) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj).

(21) Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).

(22) OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

1 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, pp. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

(29) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States and can therefore, by reason of the international and changeable nature of the trade in drug precursors, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in third paragraph of Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not exceed what is necessary for reaching those objectives. This Regulation respects the fundamental rights and observes the principles recognised, in particular, by the Charter of Fundamental Rights of the European Union.

(30) Regulations (EC) No 273/2004 and 111/2005 should therefore be repealed.

(31) The application of this Regulation should be deferred with the time needed to establish the electronic system needed for its implementation.

(32) Transitional arrangements should be set out to ensure the validity of documents issued under Regulation (EC) No 273/2004 and Regulation (EC) 111/2005 and to allow for the connection of the electronic system for competent authorities and customs systems, to guarantee legal certainty and ensure a smooth transition towards the new rules,

HAVE ADOPTED THIS REGULATION:

Chapter 1
General provisions

Article 1

Subject matter

1. This Regulation establishes harmonised rules for the monitoring and control of the making available on the market, import, export, possession, and use of drug precursors and of intermediary activities involving drug precursors with a view to ensuring their free movement in the internal market and preventing their availability for the illicit manufacture of drugs.

2. This Regulation shall apply without prejudice to other provisions of Union legislation applicable to the substances in Annex I, Annex II and Annex III.

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

(1) ‘drug precursor’ means a substance that can be used for the illicit manufacture of drugs, as well as mixtures, organisms and substances which occur in nature containing such substances;

(2) ‘drug’ means a drug as defined in Article 1, point 1 of Council Framework Decision 2004/757/JHA;[25]

(3) ‘scheduled drug precursor’ means a drug precursor consisting of or containing a substance covered by Annex I, Annex II or Annex III to this Regulation, unless it is exempted, in accordance with that Annex;

[25] 11.2004, p. 8, ELI: http://data.europa.eu/eli/dec_framw/2004/757/oj).

(4) 'non-scheduled drug precursor' means a drug precursor which, although not containing or consisting of a substance covered by Annex I, Annex II or Annex III to this Regulation, can be used for the illicit manufacture of drugs;

(5) 'substance' means a substance as defined in Article 3, point 1 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council;[26]

(6) 'mixture' means a mixture as defined in Article 3, point 2 of Regulation (EC) No 1907/2006;

(7) 'substances which occur in nature' means a substance as defined in Article 3, point 39 of Regulation (EC) No 1907/2006;

(8) 'designer precursor' means a drug precursor which is a substance or a mixture containing a substance which is a close chemical relative of a substance covered by Annex I or Annex II and which does not have any known legitimate use except research and innovation;

(9) 'medicinal product' means a medicinal product as defined in Article 1, point (2) of Directive 2001/83/EC;[27]

(10) 'veterinary medicinal product' means a veterinary medicinal product as defined in Article 4(1) of Regulation (EU) 2019/6;[28]

(11) 'making available on the market' means any supply of a drug precursor for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(12) 'use' means use as defined in Article 3, point 24 of Regulation (EC) No 1907/2006;

(13) 'import' means any entry of drug precursors having the status of non-Union goods into the customs territory of the Union, including their placement in temporary storage, transit, storage in customs warehousing and in free zones, temporary admission, end use or inward processing, and declared for their release for free circulation within the meaning of [the Proposal for a] Regulation of the European Parliament and of the Council (EU).../...[2];

(14) 'export' means the exit of a drug precursor from the customs territory of the Union, including re-export, outward processing, and the export procedure within the meaning of Regulation (EU) .../... [COM/2023/258 final, 2023/0156 (COD)];

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(26) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, pp. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

(27) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67, ELI: http://data.europa.eu/eli/dir/2001/83/oj).

(28) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43, ELI: http://data.europa.eu/eli/reg/2019/6/oj).

2 Regulation (EU) .../... of the European Parliament and of the Council establishing the Union Customs Code and the European Union Customs Authority, and repealing Regulation (EU) No 952/2013 (OJ, L, ... [PO: please add publication references for COM/2023/258 final, 2023/0156 (COD)].

(15) ‘release for free circulation’ means release for free circulation within the meaning of Title VI, Chapter 2 of Regulation (EU) .../... [COM/2023/258 final, 2023/0156 (COD)];

(16) ‘temporary storage’ means temporary storage as defined in Article 5, point (50), of Regulation (EU) .../... [COM/2023/258 final, 2023/0156 (COD)];

(17) ‘temporary admission’ means temporary admission within the meaning of Title VIII, Chapter 4, Section 1 of Regulation (EU) .../... [COM/2023/258 final, 2023/0156 (COD)];

(18) ‘inward processing’ means inward processing within the meaning of Title VIII, Chapter 5, Section 2 of Regulation (EU) .../... [COM/2023/258 final, 2023/0156 (COD)];

(19) ‘outward processing’ means outward processing within the meaning of Title VIII, Chapter 5, Section 3 of Regulation (EU) .../... [COM/2023/258 final, 2023/0156 (COD)];

(20) ‘transit’ means external transit as defined in Article 111 of Regulation (EU) .../... [COM/2023/258 final, 2023/0156 (COD)];

(21) ‘customs warehousing’ means customs warehousing within the meaning of Title VIII, Chapter 3, Section 2 of Regulation (EU) .../... [COM/2023/258 final, 2023/0156 (COD)];

(22) ‘free zone’ means free zone within the meaning of Title VIII, Chapter 3, Section 3 of Regulation (EU) .../... [COM/2023/258 final, 2023/0156 (COD)];

(23) ‘re-export notification’ means re-export notification as defined in Article 5, point (46), of Regulation (EU) .../...[COM/2023/258 final, 2023/0156 (COD)];

(24) ‘provider of an online marketplace’ means a provider of an online platform within the meaning of Article 3, point (i), of Regulation (EU) 2022/2065[(31)] that allows consumers or operators to conclude distance contracts with traders for the sale of scheduled drug precursors;

(25) ‘intermediary' means any natural or legal person arranging the purchase and sale or supply of scheduled drug precursor, where the goods subsequently will be imported or exported and aiming to obtain an agreement between two parties or to do so through acting on behalf of at least one of these parties without taking these drug precursors into their possession or taking control of the carrying out of such transaction; this definition shall also pertain to any activity involving purchase and sale or supply of scheduled drug precursors without these precursors being introduced into the Union customs territory;

(26) ‘operator’ means any natural or legal person making available on the market, possessing or using drug precursors or any external trader of such precursors;

(27) 'external trader' means any importer, exporter, or intermediary of drug precursors;

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(31) Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/2065/oj).

(28) 'name of a substance covered by Annex I, Annex II or Annex III' means either the name of the substance as listed in Annex I, Annex II or Part I, of Annex III to this Regulation for substances identified individually, or the International Union of Pure and Applied Chemistry (IUPAC) name of the substance identified in a generic way, followed by the name of the generic group, as stated in this Regulation;

(29) 'importer' means importer as defined in Article 5, point (12), of Regulation (EU) .../... [COM/2023/258 final, 2023/0156 (COD)];

(30) 'exporter' means exporter as defined in Article 5, point (14), of COM/2023/258 final, 2023/0156 (COD);

(31) 'customs representative' means customs representative as defined in Article 5, point (15), of Regulation (EU) .../... [COM/2023/258 final, 2023/0156 (COD)];

(32) 'carrier' means carrier as defined in Article5, point (25), of Regulation (EU) .../... [COM/2023/258 final, 2023/0156 (COD)];

(33) 'ultimate consignee' means any natural or legal person to whom the scheduled drug precursors are delivered from or to a third country; this person may be different from the end-user;

(34) 'suspicious transaction' means any transaction concerning drug precursors for which there are reasonable grounds for suspecting that the drug precursors concerned are intended for the illicit manufacture of drugs;

(35) 'seizure' means the temporary prohibition of the transfer, destruction, conversion, disposal or movement of drug precursors or temporarily assuming custody or control of drug precursors;

(36) 'International Narcotics Control Board' means the Board established by the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol;

(37) 'the Agency' means the European Union Drugs Agency established by Regulation (EU) 2023/1322 of the European Parliament and of the Council[32].

Article 3

Scope

1. This Regulation shall apply to scheduled drug precursors, which are:

(a) substances covered by Annex I, Annex II or Annex III;

(b) mixtures containing substances covered by Annex I, Annex II or Annex III, except if:

(i) the substance cannot be easily used or extracted by readily applicable or economically viable means; or

(ii) the substance is below the concentration threshold set out in Annex I, Annex II or Annex III and, where applicable, does not meet the special conditions set out in Annex I, Annex II or Annex III;

[32] Regulation (EU) 2023/1322 of the European Parliament and of the Council of 27 June 2023 on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006 (OJ L 166, 30.6.2023, p. 6, ELI: http://data.europa.eu/eli/reg/2023/1322/oj).

(c) organisms or parts thereof and substances which occur in nature, which contain substances covered by Annex I, Annex II or Annex III, unless the condition set out in point (b)(i) is met;

2. This Regulation shall also apply to non-scheduled drug precursors which are substances that can be used for the illicit manufacture of drugs, and mixtures containing such substances, unless the condition in paragraph 1, point (b)(i) is met.

3. This Regulation shall not apply to the following operators:

(a) customs, police, armed forces and official laboratories of competent authorities in so far as these operators act within the scope of their official duties;

(b) pharmacies and dispensaries of veterinary medicinal products possessing or using Category 1 or Category 2 drug precursors, within the scope of their regular activities.

4. This Regulation shall not apply to:

(a) making available on the market, possession or use of medicinal products or veterinary medicinal products;

(b) import, export or intermediary activities with medicinal products or veterinary medicinal products except those listed in Part II of Annex II.

Article 4

Free movement

Unless otherwise provided for in this Regulation or in other legal acts the Union, Member States shall not prohibit, restrict or hinder making available on the market of scheduled drug precursors by operators complying with this Regulation on grounds related to monitoring the legitimate trade for the prevention of the illicit manufacture of drugs.

Article 5

Categories of scheduled drug precursors

1. Scheduled drug precursors shall belong to one of the following categories:

(a) Category 1 drug precursors containing or consisting of substances covered by Annex I;

(b) Category 2 drug precursors:

(i) containing or consisting of substances covered by Part I, of Annex II; or

(ii) medicinal products and veterinary medicinal products containing substances covered by Part II, of Annex II;

(c) Category 3 drug precursors containing or consisting of substances covered by Annex III which are designer precursors with no known legitimate use except research and innovation at the moment of their scheduling. The substances covered by Annex III shall be either listed individually or identified in a generic way by listing groups of substances. Individual substances included in such a group that have a legitimate use other than research and innovation and that are not included in Annex I or Annex II, shall be exempted from Category 3 and listed in Part II, Section 2, of Annex III.

2. Scheduled drug precursors which are mixtures containing substances covered by Annex I above the concentration threshold set out in that Annex, organisms or substances which occur in nature containing such substances, and in addition containing substances covered by Annex II or Annex III shall be subject to the requirements for Category I drug precursors.

3. Scheduled drug precursors, which are mixtures containing substances covered by Annex III above the concentration threshold set out in that annex, organisms or substances which occur in nature containing such substances, and in addition containing substances covered by Annex II shall be subject to the requirements for Category 3 drug precursors.

4. Scheduled drug precursors containing or consisting of a substance covered by Annex I or Annex II, which are also identified in a generic way in Part II, Section 1, of Annex III shall be subject to the requirements for Category 1 or, respectively, Category 2 drug precursors.

Chapter 2
Obligations of operators

SECTION 1
COMMON PROVISIONS

Article 6

Obligation of cooperation

1. Operators shall provide accurate, complete and up-to-date information to the competent authority or customs authorities of the Member State concerned when fulfilling their obligations under this Regulation.

2. Operators shall, further to a reasoned request, provide competent authorities or customs authorities with the information and documentation necessary to demonstrate that they fulfilled their obligations based on this Regulation, without delay, in a machine-readable and structured way, using open standards, transferred through a secure communication channel without vendor lock-in.

3. Operators shall cooperate with those authorities, upon request, on any action taken to eliminate the risks of diversion of scheduled drug precursors towards the illicit manufacture of drugs.

Article 7

Documentation

1. Operators making available on the market, importing, exporting and performing intermediary activities with scheduled drug precursors shall keep commercial documents for each transaction, which will include the following information:

   (a) the name of the substance covered by Annex I, Annex II or Annex III, or, in the case of a mixture or a an organism or a substance which occurs in nature, their name and the name of the substance covered by Annex I, Annex II or Annex III, contained in the mixture, organism or substance which occurs in

nature; for import, export or intermediary activities, the name shall be followed by the term 'DRUG PRECURSOR';

(b) the quantity of the substance covered by Annex I, Annex II or Annex III and, in the case of a mixture, an organism or a substance which occurs in nature, the quantity or the percentage of any such substance contained therein; and

(c) the names and addresses of the other operators involved in the transaction.

2. Operators shall keep the documentation referred to in paragraph 1 for a period of 5 years from the end of the calendar year in which the transaction took place.

Article 8

Provision of information on suspicious transactions, disappearances and thefts

1. Operators shall report to the competent authorities immediately suspicious transactions, significant disappearances and thefts of scheduled drug precursors. Where providers of online marketplaces become aware of any information regarding suspicious transactions, significant disappearances, and thefts of scheduled drug precursors, they shall immediately report that information to the competent authorities.

2. For the purposes of paragraph 1, operators and providers of online marketplaces shall provide any available information, such as:

(a) the name of the substance covered by Annex I, Annex II or Annex III;

(b) the quantity of the substance;

(c) the names and addresses of the operators involved in the supply chain.

SECTION 2
CATEGORY 1 DRUG PRECURSORS

Article 9

Licence

1. Without prejudice to paragraph 7, operators shall obtain a licence from the competent authorities of the Member State in which they are established before they make available on the market, import, export, perform intermediary activities, possess or use Category 1 drug precursors in quantities exceeding the quantity thresholds set out in Annex I over one calendar year. This obligation shall not apply to:

(a) direct customs representatives, carriers and other transporters acting solely in that capacity;

(b) Category 1 drug precursors which are transhipped, placed under temporary storage, stored in a free zone, or leaving the customs territory of the Union by a re-export notification.

2. When considering whether to grant a licence, the competent authorities shall take into account the conditions set out in Annex IV regarding the competence and integrity of the applicant. The licence shall be refused if there are reasonable grounds for doubting the suitability and reliability of the operator or its responsible officer.

3. The licence shall include the information set out in Annex IV and shall be granted for a period not exceeding three years, unless the operator requests it for a shorter time period.

4. The competent authorities may grant simplified licences for an unlimited time period, subject to the conditions set out in Annex IV.

5. Operators shall inform the competent authority of any changes to the activities to be performed, the scheduled drug precursors or the relevant quantities during the validity period of the licence, which would require an update of the licence already granted.

6. The licence may be suspended or revoked by the competent authorities whenever the conditions under which the licence was granted are no longer fulfilled or where there are reasonable grounds for suspecting that there is a risk of diversion of scheduled drug precursors towards the illicit manufacture of drugs.

7. External traders that import, export, or perform intermediary activities with Category 1 drug precursors in quantities not exceeding the quantity thresholds set out in Annex I over one calendar year shall be subject to the obligations applicable under Article 15.

8. The competent authorities may require operators to pay a fee for processing the application for a licence. Where a fee is levied, competent authorities shall adjust the level of the fee set for small and medium-sized enterprises. Such a fee shall be levied in a non-discriminatory manner and shall not exceed the cost of processing the application.

Article 10

Responsible officer

1. Operators referred to in Article 9(1) shall appoint a responsible officer established in the Union empowered to represent them in matters relating to the application of this Regulation.

2. The responsible officer shall be empowered to take all decisions needed to ensure that the activities performed by the operator comply with this Regulation.

Article 11

Labelling

Operators making available on the market, importing, exporting, or performing intermediary activities with Category 1 drug precursors shall ensure that the name of the substance covered by Annex I is indicated on the packaging or its label, or, in case of products supplied in bulk, in the accompanying documents.

Article 12

Documentation for use or possession

1. Operators using or possessing Category 1 drug precursors shall keep documentation on their activities in accordance with Article 7(1).

2. The operators referred to in paragraph 1 shall keep the documentation for a period of 5 years from the end of the calendar year in which the specific drug precursor was possessed for the last time.

Article 13

Verification of operators

Operators shall make available on the market Category 1 drug precursors only after having verified that the other operators involved in such a transaction hold a valid licence.

Article 14

Securing premises

Operators shall take adequate measures to secure business premises and the places of use against the unauthorised removal of Category 1 drug precursors.

SECTION 3
CATEGORY 2 DRUG PRECURSORS

Article 15

Registration

1. External traders engaged in import, export or intermediary activities involving Category 2 drug precursors shall register information on their activities with the competent authority in the Member State where they are established. This obligation shall not apply to:

   (a) direct customs representatives, carriers and transporters when acting solely in those capacities;

   (b) Category 2 drug precursors transhipped, placed under temporary storage, stored in a free zone, or leaving the customs territory of the Union by a re-export notification.

2. The registration shall include the information set out in Annex V and shall be made for a period not exceeding three years.

3. By way of derogation from paragraph 2, a registration may be valid for an unlimited period of time, subject to the conditions set out in Annex V.

4. The external traders referred to in paragraph 1 shall update the information in the registration, as needed, in accordance with Annex V.

5. The competent authority in the Member State of establishment of the external trader may order the external trader to suspend or cease the activities covered by the registration, where the registration does not comply with this Regulation; the conditions declared are no longer fulfilled; or, where there are reasonable grounds for suspecting that there is a risk of diversion of the scheduled drug precursors towards the illicit manufacture of drugs.

6. The external traders referred to in paragraph 1 shall appoint a responsible officer in accordance with Article 10.

7. The external traders referred to in paragraph 1 shall ensure that the name of the substance covered by Annex II is indicated on the packaging or its label, or, in case of products supplied in bulk, in the documents accompanying them.

SECTION 4
CATEGORY 3 DRUG PRECURSORS

Article 16

Ban

1. The making available on the market, import, export, possession, use of Category 3 drug precursors, and performing intermediary activities involving such drug precursors shall be prohibited.

2. By way of derogation from paragraph 1, operators may tranship Category 3 drug precursors, place them under temporary storage, store them in a free zone, or re-export them from the customs territory of the Union by a re-export notification.

Article 17

Prior notification for research and innovation

1. By way of further derogation from Article 16(1), operators may make available on the market, import, export, perform intermediary activities, possess and use Category 3 drug precursors subject to the conditions set out in this Article.

2. Operators intending to make available on the market, import, export, possess, use, or perform intermediary activities involving Category 3 drug precursors for research and innovation in quantities not exceeding the maximum quantity threshold set out in Part I of Annex III shall notify their intended activities over a period of maximum six months to the competent authority in the Member State where they are established, 5 days before the first transaction or possession. This obligation does not apply to direct customs representatives, carriers and other transporters acting solely in that capacity.

3. The prior notification referred to in paragraph 2 shall include the information set out in Annex VI.

4. The competent authority may request additional information and perform inspections to check the accuracy of the information provided, including the use of drug precursors for research and innovation.

5. The competent authority of the Member State of establishment of the operator may order the operator to suspend or cease the activities covered by the prior notification, where the prior notification does not comply with this Regulation; the conditions declared are no longer fulfilled; or, there are reasonable grounds for suspecting that there is a risk of diversion of the Category 3 drug precursor towards the illicit manufacture of drugs.

Article 18

Licence for Category 3 precursors

By way of further derogation from Article 16(1), operators may make available on the market, import, export, perform intermediary activities, possess or use Category 3 drug precursors for

research and innovation in quantities exceeding the maximum quantity threshold set out in Part I of Annex III or for other legitimate use, provided they obtain a licence in accordance with Article 9(1), (2) and (3). Article 9(5), (6) and (8) shall also apply to that licence.

Article 19

Additional obligations for Category 3 drug precursors

1. Operators referred to in Article 17 or Article 18 shall make available on the market Category 3 drug precursors only after having verified that the operators involved in the transaction have made a prior notification or hold a licence in accordance with Article 17 or Article 18 respectively.

2. Operators using or possessing Category 3 drug precursors subject to the conditions set out in Article 17 or Article 18 shall keep documentation on their activities in accordance with Article 12.

3. Operators referred to in Article 17 and Article 18 shall meet the following obligations:

   (a) appoint a responsible officer in accordance with Article 10;

   (b) secure premises in the conditions set out in Article 14.

4. External traders importing, exporting or performing intermediary activities with Category 3 drug precursors in accordance with Article 17 and Article 18 shall ensure that the name of the substance covered by Annex III is indicated on the packaging or its label, or, in case of products supplied in bulk, on the accompanying documents.

SECTION 5
EXTERNAL TRADE

Article 20

Import

1. The importer shall notify the competent authority of the total quantity of the intended imports for each substance covered by Annex I or Annex II over a specified time period before the first import. The quantity of substances imported during that time period shall not exceed the quantities notified.

2. Paragraph 1 shall also apply for imports of substances covered by Annex III, subject to the conditions set out in Article 17 or Article 18.

3. The information to be provided in accordance with paragraphs 1 and 2 is set out in Chapter 1, of Annex VII.

4. Where the substances referred to in paragraph 1 and paragraph 2 are transhipped, placed under temporary storage, inward processing, transit, in customs warehousing, or stored in a free zone, paragraph 1 and paragraph 2 shall not apply.

Article 21

Pre-export notification

1. All exports of Category 1 drug precursors and exports of Category 2 drug precursors to certain countries of destination, as referred to in Chapter 2 of Annex VII, shall be

preceded by a pre-export notification by the competent authorities of the Member State concerned to the competent authorities of the country of destination.

2. Exports of Category 3 drug precursors, subject to the conditions set out in Article 17 or Article 18, shall also be preceded by a pre-export notification, as set out in paragraph 1.

3. The pre-export notification shall be waived for exports from the Union to a third country or territory outside the customs territory of the Union where that third country or territory is also part of the Union single market or there is an international agreement between the Union and a third country or territory waiving the pre-export notification.

4. Operators shall inform competent authorities of the Member State of establishment of their intention to export the scheduled drug precursors referred to in paragraph 1 and paragraph 2.

5. In case the export of scheduled drug precursors is to be notified in accordance with paragraph 1 and paragraph 2, the competent authorities of the Member State concerned shall, prior to the export of such drug precursors, supply the information set out in Chapter 2 of Annex VII of the intended export to the competent authorities of the country of destination.

6. The competent authority supplying such information shall require the competent authority in the country of destination receiving the information to keep confidential any trade, business, commercial or professional secret or any trade process referred to therein.

7. Simplified pre-export notification procedures may be applied by the competent authorities under the conditions set out in Chapter 2, point 4, of Annex VII where they are satisfied that this will not result in any risk of diversion of scheduled drug precursors.

Article 22

Export

1. The exporter shall notify the competent authority of the total quantity of the intended exports for each substance covered by Annex I or Annex II in a specified time period before the first export. The quantity of substances exported during that time period shall not exceed the quantity notified.

2. Paragraph 1 shall also apply for exports of substances covered by Annex III, subject to the conditions set out in Article 17 or Article 18.

3. The information to be provided in accordance with paragraph 1 and paragraph 2 is set out in Chapter 3 of Annex VII.

4. Where the drug precursors referred to in paragraph 1 or paragraph 2 are leaving the customs territory of the Union under the transit procedure or by a re-export notification, paragraphs 1 and 2 shall not apply.

5. Whenever, under an agreement between the Union and a third country, an export requires that an import authorisation has been issued by the competent authorities of that third country for the drug precursor in question, that import authorisation shall be provided to the competent authorities in the Member State of establishment before the export can be done.

6. Following the notification referred to in Article 21(1) and Article 21(2), the competent authorities or the customs authorities of the Member States may prevent the export if an objection, indicating that this export might be intended for the illicit manufacture of drugs, is received from the competent authorities or customs authorities of the country of destination.

Article 23

Customs verification

1. For the purposes of import, except for the transit procedure, the operator holding the licence, registration, or prior notification as required under this Regulation, shall be the importer indicated in the customs declaration.

   In the case of transit procedure, the operator holding the licence, registration, or prior notification as required under this Regulation, shall be the holder of the transit procedure indicated in the customs declaration.

   For the purposes of exports, the operator holding the licence, registration, or prior notification as required under this Regulation, shall be the exporter indicated in the customs declaration.

2. The importer, exporter or holder of a transit procedure as referred to in paragraph 1 shall provide or make available to customs authorities either: proof of possession of a valid licence as referred to in Article 9 or Article 18; registration as referred to Article 9(7) or Article 15; or prior notification as referred to in Article 17, including, where applicable, the proof of notification of quantities in accordance with Articles 20 and 22.

3. Customs authorities may release a substance for a customs procedure or re-export only after having verified as a minimum that an active licence, registration, or prior notification exists, where those are required.

4. In addition to paragraph 3, the customs authorities shall verify that the quantities are within the thresholds notified in Article 20 and Article 22 before releasing substances for free circulation, temporary admission, end use, outward processing, export or re-export where a re-export declaration is submitted.

5. The release of the goods shall not be deemed to be proof of compliance with this Regulation or other Union legislation.

6. The verification referred to in paragraph 3 and paragraph 4 shall be done electronically and automatically via the interconnection referred to in Article 35(5) from the date that interconnection is operational.

7. The Commission and the customs authorities may use the data included in the electronic system referred to in Article 35 of this Regulation for carrying out their duties pursuant to Union legislation, including risk management, customs controls and release to a customs procedure within the meaning of Regulation (EU) .../... [COM/2023/258 final, 2023/0156 (COD)].

8. Paragraph 2, 3, and 4 shall not apply to drug precursors that are transhipped, placed under temporary storage, stored in a free zone, or when they are leaving the customs territory of the Union by a re-export notification.

9. Paragraph 4 shall not apply to drug precursors that are placed under customs warehousing, inward processing, or transit procedure.

Article 24

Demonstration of licit purposes

Where a scheduled drug precursor enters into the customs territory of the Union for transhipment, placement in temporary storage or storage in a free zone for licit purposes, the operator shall demonstrate those licit purposes in accordance with Chapter 4 of Annex VII, upon request by the competent authorities or the customs authorities.

Chapter 3
Awareness raising activities

Article 25

The Drug Precursors Information Repository

1. By [OP please add date: *3 years after entry into force of this Regulation*] the Agency shall establish a Drug Precursors Information Repository ('Repository').

2. The Repository shall contain information on the substances covered by Annex I, Annex II and Annex III and on other substances which can be used in the illicit manufacture of drugs, in particular:

   (a) general description of the substance and its chemical properties;

   (b) information on legitimate uses and trade;

   (c) information on the use of the substance in the illicit production of drugs.

3. If substances are as a group of substances identified in a generic way in accordance with Article 37(1), the Repository referred to in paragraph 1 shall include an indicative list of the most relevant individual substances covered by the group of substances and a specific function allowing operators to check if a specific substance is to be considered as being part of the group.

4. The information referred to in paragraph 2, points (a) and (b) and the specific function referred to in paragraph 3 shall be publicly available and free of charge.

5. The information referred to in paragraph 2, point (c) may be used by the Commission, the Agency and other Union bodies and the Member States to identify new trends in the illicit manufacture of drugs and appropriate measures.

6. The Agency shall maintain and keep the Repository up to date.

Article 26

Training activities

1. Member States shall ensure that law enforcement authorities and customs authorities are provided with training, such as risk management training, to detect, in the course of their duties, scheduled or non-scheduled drug precursors that may be used in the illicit manufacture of drugs, and to react in a timely and appropriate manner to a suspicious activity.

2. Member States shall organise, at least once a year, awareness-raising actions for operators making available on the market, importing, exporting, performing intermediary activities, possessing or using drug precursors.

3. Operators shall be responsible for providing information to their personnel on the obligations of the operators under this Regulation and for raising personnel awareness in this regard.

Chapter 4
Cooperation with and tasks of national authorities

Article 27

Administrative cooperation

1. Each Member State shall designate the competent authority or authorities responsible for ensuring the application of this Regulation and shall inform the Commission, the other Member States and the Agency thereof.

2. For the purposes of applying this Regulation, the provisions of Regulation (EC) No 515/97 shall apply with the necessary adaptations. The competent authorities designated under paragraph 1 shall act as competent authorities within the meaning of Article 2(2) of Regulation (EC) No 515/97.

Article 28

Controls by competent authorities

1. Competent authorities shall carry out controls to determine if operators fulfil the obligations laid down in this Regulation. When there is reason to believe that a drug precursor might be diverted towards the illicit manufacture of drugs, the competent authority shall perform additional controls without delay under the conditions set out in Article 29 and Article 30.

2. The competent authorities shall respect the principles of confidentiality and of professional and commercial secrecy and shall protect personal data in accordance with Union and national law.

3. Member States shall ensure that the competent authorities have the resources necessary to ensure the proper administration of their tasks under this Regulation.

Article 29

Control of internal market

Competent authorities may seize scheduled drug precursors for up to 30 days subject to the conditions set out under national law, to verify the identification of the drug precursors and compliance with this Regulation.

Article 30

Control of export and import

1. The competent authorities of each Member State shall prohibit the introduction of scheduled drug precursors into the Union customs territory or their departure from it, if there are reasonable grounds for suspecting that the drug precursors are intended for the illicit manufacture of drugs.

2. The competent authorities of each Member State shall prohibit the introduction of non-scheduled drug precursors into the customs territory of the Union or their

departure from it where there is sufficient evidence that those drug precursors are intended for the illicit manufacture of drugs.

3. Customs authorities shall detain or suspend the release of the scheduled drug precursors for the respective customs procedure, and only release them for the respective customs procedure after verifying their compliance with this Regulation.

4. The customs authorities may temporarily detain non-scheduled drug precursors for which there is suspicion that they are intended to be used in the illicit manufacture of drugs in accordance with the conditions laid down in national law.

5. The period of temporary detention referred to in paragraph 4 shall not exceed 30 days.

6. Customs authorities or competent authorities shall be empowered to carry out controls and monitor suspicious transactions during import and export involving scheduled or non-scheduled drug precursors, including:

   (a) obtaining information on any orders for or activities involving import, export and transit of scheduled or non-scheduled drug precursors;

   (b) entering the business premises of operators in order to obtain evidence of irregularities;

   (c) establishing that a diversion or attempted diversion of scheduled drug precursors has taken place, and carry out follow up measures, where required.

7. When determining if there is suspicion that scheduled or non-scheduled drug precursors are intended to be used in the illicit manufacture of drugs, customs authorities or competent authorities shall use the criteria laid out in Chapter 5 of Annex VII. Should the criteria laid out in chapter 5, point 8 (b), of Annex VII be fulfilled the external trader importing, exporting, or performing intermediary activities with the non-scheduled substance shall be required to prove that the substance is destined for legitimate use.

8. For the purpose of preventing specific risks of diversion of drug precursors stored in free zones and under temporary storage as well as in other sensitive areas, such as customs warehouses, Member States shall ensure that effective controls are applied to activities carried out in these areas at every stage, and that the controls are no less stringent than those applied in the other parts of the customs territory.

Article 31

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented.

The penalties provided for shall be effective, proportionate and dissuasive.

Member States shall notify the Commission of those rules and of any subsequent amendment affecting them.

Article 32

Reporting obligation

The competent authorities and customs authorities shall report information on seizures of drug precursors and information on the implementation of this Regulation subject to the conditions set out in Annex VIII.

Article 33

Obligation of information

1. Where the information referred to in Article 32 concerns significant seizures of non-scheduled drug precursors, the competent authority or customs authority shall notify the Commission, the Agency and other Member States without delay.

2. The competent authority of a Member State shall inform the Commission, the Agency and the competent authorities of other Member States without delay, if it receives a request for a licence for a Category 3 drug precursor in accordance with Article 18.

Article 34

UN reporting

The Commission shall, in consultation with Member States, submit an annual report to the International Narcotics Control Board based on information provided by operators and competent authorities, subject to the conditions set out in Annex VIII.

Chapter 5
Drug precursors electronic system

Article 35

Electronic system

1. The Commission shall establish and maintain a centralised electronic system for the submission, storage, processing, decision-making, and exchange of information for the monitoring and control of drug precursors in accordance with this Regulation.

2. The Commission shall establish the electronic system referred to in paragraph 1, in particular with the following functions:

   (a) To enable operators to:

      (i) register in the system in order to perform formalities set out in this Regulation;

      (ii) request a licence in accordance with Article 9 and Article 18;

      (iii) make the registration required by Article 9(7) and Article 15;

      (iv) file a prior notification in accordance with Article 17(2);

      (v) verify in accordance with Article 13 and Article 19(1) that other operators hold a licence or made a prior notification;

      (vi) notify quantities to competent authorities in accordance with Articles 20 and 22;

   (b) To enable operators and providers of online marketplaces to report on suspicious transactions in accordance with Article 8;

(c) To enable competent authorities to:

(i) issue, suspend or revoke a licence;

(ii) order operators to suspend or cease activities covered by a registration or a prior notification, in accordance with Article 15(5) or Article 17(5) respectively;

(iii) provide information in accordance with Article 32 and Article 33;

(d) facilitate the preparation of the report to the International Narcotic Control Board in accordance with Article 34, by the Commission in consultation with Member States.

3. The functions referred to in paragraph 2, points (a)(i), (ii), (iii), (iv) and (v), points (b), (c) and (d) shall be operational at the latest 18 months after the entry into force of the implementing act referred to in paragraph 8.

4. The functions referred to in paragraph 2, point (a)(vi) shall be operational at the latest 6 years after the entry into force of the implementing act referred to in paragraph 8.

5. The Commission shall interconnect the electronic system referred to in paragraph 1 with the EU Single Window Environment for Customs established by Regulation (EU) 2022/2399 for the purpose of enabling the performance of the verifications referred to in Article 23(3) and Article 23(4) at the latest 6 years from the entry into force of the implementing act referred to in paragraph 8 of this Article.

6. The Commission may, in cooperation with the United Nations, interconnect the system referred to in paragraph 1 with the systems of the United Nations for incidents reporting or other United Nations systems for drug precursors.

7. The Commission, the Agency, the competent authorities and the operators shall have access to the data in the electronic system needed for performing their tasks under this Regulation

8. By [*OP please add date: 18 months after the entry into force of this Regulation*], the Commission shall adopt an implementing act establishing implementing arrangements for the development and operation of the electronic system, including technical specifications and the procedures to be followed for the implementation of Articles 6, 8, 9, 13, 15, 17, 18, 19(1), 20, 21, 22, 23, 32, 33 and 34.

9. The implementing act referred to in paragraph 8 shall be adopted in accordance with the examination procedure referred to in Article 40(2).

Article 36

Data protection

1. The processing of personal data within the electronic system referred to in Article 35 shall be carried out in compliance with Regulation (EU) 2016/679 or Regulation (EU) 2018/1725, as applicable.

2. The processing of personal data under this Regulation shall take place solely for the purposes established in this Regulation.

3. Access to personal data shall be limited to duly authorised staff of the Commission and other Union bodies, competent authorities and customs authorities to the extent necessary for the performance of their tasks under this Regulation. Those Union bodies and authorities shall ensure the confidentiality and integrity of such data and

protect them against unauthorised access, use or disclosure, in accordance with the applicable Union data protection rules.

Chapter 6
Delegation of powers and committee procedure

Article 37

Delegation of power

1. The Commission is empowered to adopt delegated acts in accordance with Article 38 amending Annex I, Annex II and Annex III to adapt those Annexes to new trends in diversion of drug precursors or to align them with any amendment to the tables annexed to the UN Convention, by adding or removing substances and adapting existing entries. The Commission may only add substances identified individually to Annex I or Annex II, unless otherwise required to align those Annexes with the tables annexed to the UN Convention. The Commission may add substances in Annex III either identified individually or in a generic way. When adding substances in a generic way, the Commission shall clearly identify the group of substances and, if applicable, the individual substances which are to be exempted from the control and monitoring measures for scheduled drug precursors.

2. When a substance covered by Annex III has legitimate use other than in research and innovation, as reported in accordance with Article 33(2), where applicable, the Commission shall adopt a delegated act amending that Annex by removing the substance from Part I of that Annex and, as appropriate, including it in Annex I or Annex II or in the exemption list in Part II, Section 2 of Annex III.

3. When adopting delegated acts in accordance with paragraphs 1 and 2, the Commission shall also indicate for the substances concerned:

   (a) the concentration threshold for a substance in Annex I, II or III below which and, where appropriate, the special conditions under which a mixture containing that substance is excluded from the scope of this Regulation in accordance with Article 3(1), point (b)(ii);

   (b) a quantity threshold during one calendar year below which the obligations set out in Article 9(1), first subparagraph, do not apply;

   (c) a maximum quantity threshold which can be notified for use in research and innovation, in the conditions laid down in Article 17(2), as applicable.

   The Commission shall adopt delegated acts amending Annex I, Annex II and Annex III to set up the thresholds referred to in the first subparagraph, points (a), (b) and (c), for substances already included in those Annexes.

4. The Commission is empowered to adopt delegated acts amending Annex IV, Annex V, Annex VI, Annex VII, Annex VIII and Annex IX to adapt the general conditions and other technical rules for: licences; registrations; prior notifications; quantity notifications for import or export; pre-export notifications; the criteria to determine the licit purposes of the transaction referred to in Article 24; determining the criteria for suspicion on intention of use in the illicit manufacture of drugs as referred to in Article 30(7); reporting obligations; and transitional measures.

5. When adopting delegated acts in accordance with this Article, the Commission shall take into account both the risk of diversion of drug precursors for the production and manufacture of illicit drugs and the impact on legitimate trade.

Article 38

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 37 shall be conferred on the Commission for a period of five years from [*OP please add date: the date of entry into force of this Regulation*]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 37 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State acting in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 37 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 39

Urgency procedure

1. Delegated acts amending Annex I, Annex II and Annex III adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 38. In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

Article 40

Committee procedure

1. The Commission shall be assisted by the Drug Precursors Committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Chapter 7
Transition and final provisions

Article 41

Review

By [*OP please add date: 10 years from the date of application of this Regulation*], the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation. The report shall contain an assessment of how this Regulation is achieving its objectives.

Article 42

Repeal

1. Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 are repealed.

2. References to the repealed Regulations shall be construed as references to this Regulation and read in accordance with the correlation table in Annex X.

Article 43

Transitional provisions on licences, registrations and import and export authorisations issued or applied for under Regulations (EC) No 273/2004 or (EC) No 111/2005

1. Licences, special licences, registrations and special registrations issued under Regulation (EC) No 273/2004 or Regulation (EC) No 111/2005 before [*OP please add date: 3 years after the date of entry into force of this Regulation*] shall be valid until their expiry date or until [*OP please add date: 4 years after the date of entry into force of this Regulation*] whichever is soonest.

2. Licences and special licences for which an application is made before [*OP please add date: 3 years after the date of entry into force of this Regulation*] based on Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 shall be granted in accordance with those Regulations and be valid until maximum [*OP please add date: 4 years after the date of entry into force of this Regulation*].

3. When relevant, licences, special licences, registrations and special registrations issued under Regulation (EC) No 273/2004 or Regulation (EC) No 111/2005 shall be revoked or suspended pursuant to those Regulations for the duration of the transitional period.

4. Import and export authorisations issued under Regulation (EC) No 111/2005 before [*OP please add date: 3 years after the date of entry into force of this Regulation*] shall be valid until their expiry date.

5. Import and export authorisations applied for under Regulation (EC) No 111/2005 but not issued before [*OP please add date: 3 years after the date of entry into force of this Regulation*] shall be deemed to have been applied for under the conditions set out in Annex IX.

Article 44

Transitional rules on import and export authorisations and reporting

From the date of application of this Regulation and until the function referred to in Article 35(2), point (a)(vi) is operational, the transitional rules on import and export authorisations and reporting provided for in Annex IX shall apply.

Article 45

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in t*he Official Journal of the European Union.*

It shall apply from [*OP please add date: 3 years after the date of entry into force of this Regulation]*.

However, Article 25, Article 35(8) and (9), Articles 37, 38, 39, 40 and this article shall apply from [*OP please add: date of entry into force of this Regulation*], and Articles 20, 22, and 23 shall apply when the function referred to in Article 35(2), point (a)(vi) is operational.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*
[...]	*[...]*

LEGISLATIVE FINANCIAL AND DIGITAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Regulation of the European Parliament and Council on monitoring and controlling drug precursors and repealing Regulations (EC) No 273/2004

1.2. Policy area(s) concerned

Internal Market

Customs Union

External Trade

1.3. Objective(s)

1.3.1. General objective(s)

There are two general policy objectives to be pursued when revising the regulations:

Objective 1: to reduce the availability of drug precursors for illicit drug manufacturing

Objective 2: to facilitate legitimate trade and use of drug precursors, both in the Internal Market and in relation to external trade

1.3.2. Specific objective(s)

Specific objective SO No 1.1 - To establish more effective and rapid control measures to address designer precursors

The aim of SO 1.1 is to ensure that rules do not only address traditional drug precursors but also newly emerging designer precursors, for which a global approach is crucial.

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

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

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

SO 2.1 is about removing unnecessary obstacles and administrative burdens for legal trade in drug precursors.

1.3.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

For Objective 1, Member States and operators will have to implement a new ban on designer precursors, that are chemically viable and easy to use, identified with sufficient precision to allow operators to conduct due diligence checks on their portfolios. For Member State authorities, the ban entails an extension of the scope of existing control and monitoring rules.

Other measures include requiring online marketplaces service providers to notify suspicious transactions, disappearances and thefts.

National authorities and customs authorities are being empowered to seize and confiscate both scheduled and non-scheduled drug precursors, if there are reasonable grounds or evidence that the drug precursor is intended for illicit use. In the internal market, Member States remain competent to adopt national rules to investigate such cases, and no additional requirements should be set out in this Regulation.

Ultimately, the measures are aimed at reducing the supply of illicit drugs with corresponding indirect effects on drug consumption, public health, and crime, even if this is not directly measurable.

For Objective 2, Member States and operators will rely on a centralised EU portal that will streamline and support the process for managing licences, registrations, customer verifications, import/export quantity management, and prior notifications. The new rules will also eventually remove periodic reporting obligations for operators and authorities.

Comprehensive digital solutions are expected to facilitate the completion of administrative tasks for operators and to expedite the overall process. Moreover, it will enable competent authorities to verify the legality of drug precursors movements more effectively, improving traceability.

From a customs perspective, digitalisation will enhance the effectiveness and efficiency of controls, providing authorities with faster access to structured, high-quality information that allows for automatic checks of licences/registrations and perform quantity management. This will support faster clearance times for imports and exports while strengthening the EU's ability to detect and prevent illicit trade.

1.3.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

Indicator linked to objective 1:

A substantial reduction of availability of precursors for illicit drug manufacturing, based on the annual volume of seized scheduled precursors (2 100 incidents, corresponding to approximately 541 tonnes of precursors seized in 2023, reporting based on the EU database of drug precursors). Previous interventions lead to a reduction of about 60 %.

Indicator linked to objective 2:

A reduction of net administrative burdens for businesses of EUR M 19.84, down from a baseline of annual recurrent costs of EUR M 32.34. This is to be verified by an evaluation no later than 10 years after the entry into application of the revised rules.

1.4. The proposal/initiative relates to:

☑ **a new action**

☐ **a new action following a pilot project/preparatory action** [1]

☑ **the extension of an existing action**

☐ **a merger or redirection of one or more actions towards another/a new action**

[1] As referred to in Article 58(2), point (a) or (b) of the Financial Regulation.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

The new rules for the internal market for drug precursors will start applying to economic operators and national authorities 2 years after the adoption of the new rules.

Amongst others, they concern the ban of designer precursors, the need for prior notifications and the verification of customers.

Experience with developing the system of past projects of integrating certificates in the EU CSW-CERTEX, shows that a period of three years after entry into force of the implementing acts is required to specify, develop, test and deploy the connection of the central e-licensing solution with quantity management, after which three years are needed for the EU CSW-CERTEX interconnection with the national customs systems.

The digitalisation of the supervision of imports, exports and licit trade of drug precursors will replace current procedures, some of which remain paper-based. It will enable a swift and secure electronic communication between actors: economic operators, their customers, competent and customs authorities in Member States.

Once the electronic system has been developed and deployed by the Commission, Member States Customs authorities are expected to connect to it via the EU Customs Single Window – CERTEX (EU CSW-CERTEX).

Competent authorities for single market matters will connect through another affiliated IT system. The IT system for formalities in the internal market will be operational 2 years after the entry into force of the regulation. The Commission will explore how existing IT systems with a similar purpose could be re-used, such as, for instance, the Single Market Compliance Space (SMCS), or the software used for the Digital Waste Shipment System (DIWASS) which will be used for the exchange of documents and information as of 21 May 2026. The DIWASS should be interoperable with other systems and software that are used by some competent authorities or economic operators, as set out in Commission Implementing Regulation (EU) 2025/1290.

Budgetary needs for the internal market IT system managed by GROW are estimated to amount to EUR M 1.070 starting from 2028.

To proceed with the preparations for an electronic system for the control of trade in drug precursors, financial and human resources need to be allocated to TAXUD as soon as possible, starting from 2025. A preliminary analysis based on the possible re-use of the Commission's electronic licensing systems and building on experience from other e-Licensing systems and the EU Customs Single Window, led to a budget requirements estimation of up to EUR M 25, depending on the IT solution delivery model chosen, for a period from 2025 to 2034(including time dedicated to the preparation of the Implementing Act). The subsequent yearly maintenance cost of the digitalisation of controls at the external borders is estimated at EUR M 0.5. The EUDA will deliver an information repository of drug precursors which will cover all relevant scheduled and non-scheduled substances having or not a known industrial or commercial use which will cost approximately 0.182 M. For the current MFF, the need for additional resources (one contractual agent post) for EUDA will be covered by a contribution agreement to be financed from the existing envelope of the

Customs Programme (DG TAXUD) up to and including 2030. The funding for a second additional FTE as of 2028 until 2030 will be covered by the amounts in the EU Facility otherwise foreseen to fund actions in the domain of Home Affairs.

Overall, the digitalisation part of this initiative is aligned with the EU digital strategy to increase the efficiency of public services, improving the quality of communication with economic operators.

1.5.2. Added value of EU involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this section 'added value of EU involvement' is the value resulting from EU action, that is additional to the value that would have been otherwise created by Member States alone.

Reasons for action at EU level (ex-ante):

The two current EU drug precursors regulations set the rules for the legitimate trade of chemical substances, respectively within the EU and with third countries, that can also be used in illicit drug production. The monitoring and control of trade between the EU and non-EU countries falls under a policy area where the EU has exclusive powers and, therefore, the subsidiarity principle does not apply.

For the internal market, any changes to the scope or requirements of such rules must be made at EU level to avoid: (i) distorting the market; (ii) creating barriers to the free movement of products; or (iii) undermining efforts to prevent diversion of drug precursors.

Expected generated EU added value (ex-post):

EU action would have clear benefits for businesses, national authorities and society as a whole, by simplifying licit trade flows between legitimate businesses within the single market and third countries, and by supporting the fight against illicit drug production. This will also remove unnecessary administrative burdens and reduce those that are necessary for supervising trade flows, such as licenses, registrations or prior notifications.

By ensuring uniform rules instead of 27 different sets of rules and procedures, EU action strengthens the competitiveness of EU businesses.

A fully digitised environment also offers advantages such as an increased effectiveness and speed of controls.

1.5.3. Lessons learned from similar experiences in the past

The evaluation of EU rules on drug precursors (Regulation (EC) No 273/2004 and Council Regulation 111/2005) found several shortcomings, especially concerning designer precursors (drug precursors with no known legitimate use except research and innovation).

Equally, it highlighted opportunities to simplify the complex legal framework and improve procedures for legitimate trade of drug precursors, thus reducing administrative burdens.

From an enforcement perspective, it demonstrated possibilities for quicker action from Member States, based on a more uniform application of rules.

Experience has shown that industry and Member States authorities need sufficient time to familiarise themselves with new requirements and to adapt their business processes accordingly.

Developing the IT system of past projects of integrating certificates in the EU CSW-CERTEX, shows that a period of three years after entry into force of the implementing acts is required to specify, develop, test and deploy the connection of the central e-licensing solution with quantity management, after which three years for the EU CSW-CERTEX interconnection with the national customs systems are needed. The synergies with the existing e-Licensing platforms are key, using a comprehensive online platform for processing applications and issuing licences, brings further harmonisation of the applied procedures. It is however to be noted that the drug precursors project presents certain particularities when compared to existing systems, and this will have to be reflected in its architecture.

1.5.4. Compatibility with the multiannual financial framework and possible synergies with other appropriate instruments

Synergies are expected through an improvement in the enforcement of rules on illicit drug trafficking and a stronger cooperation with the EU Drugs Agency (EUDA). Scheduled drug precursors are part of the material scope of minimum national rules on criminal acts concerning precursors set out by Member States in accordance with Council Framework Decision 2004/757/JHA on combatting drug trafficking. By extending the scope of substances scheduled, the application of the Framework Decision is expected to be strengthened.

The initiative also reduces administrative and reporting requirements for economic operators and national authorities.

1.5.5. Assessment

The costs incurred between 2025 and 2027 for DG TAXUD will be covered by the Customs programme. The amount of around EUR M 1.3 will be financed by the financial envelope allocated to the Customs programme under the Commission's MFF 2021-2027. The next financial envelope allocated to the Customs programme in the next MFF should cover the remaining costs of fully digitalising the drug precursors domain. The costs depend on the IT solution delivery model and might be up to additional around EUR M 24 (see below tables). That amount, estimated in the period 2028-2034, is subject to the revision of the related rates of the new DG TAXUD framework contracts that will be revised presumably in 2028. In addition, from 2035 onwards, an annual maintenance fee for this system of EUR M 0.5 should be foreseen. The post-2027 figures are indicative, without pre-empting and pre-judging the Commission proposal and the agreement on the next MFF.

For the internal market aspects of the proposal, no costs will be incurred under the current MFF.

1.6. Duration of the proposal/initiative and of its financial impact

☐ **limited duration**

- ☐ in effect from [DD.MM]YYYY to [DD.MM]YYYY
- ☐ financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☑ **unlimited duration**

Implementation with a start-up period from 2025 to 2032,

followed by full-scale operation.

1.7. Method(s) of budget implementation planned[(2)]

☑ **Direct management** by the Commission

- ☑ by its departments, including by its staff in the Union delegations;
- ☐ by the executive agencies

☐ **Shared management** with the Member States

☐ **Indirect management** by entrusting budget implementation tasks to:

- ☐ third countries or the bodies they have designated;
- ☐ international organisations and their agencies (to be specified);
- ☐ the European Investment Bank and the European Investment Fund;
- ☑ bodies referred to in Articles 70 and 71 of the Financial Regulation;
- ☐ public law bodies;
- ☐ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees;
- ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees;
- ☐ bodies or persons entrusted with the implementation of specific actions in the common foreign and security policy pursuant to Title V of the Treaty on European Union, and identified in the relevant basic act
- ☐ bodies established in a Member State, governed by the private law of a Member State or Union law and eligible to be entrusted, in accordance with sector-specific rules, with the implementation of Union funds or budgetary guarantees, to the extent that such bodies are controlled by public law bodies or by bodies governed by private law with a public service mission, and are provided with adequate financial guarantees in the form of joint and several liability by the controlling bodies or equivalent financial guarantees and which may be, for each action, limited to the maximum amount of the Union support.

Comments

[...]

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

The impact of the initiative will be assessed through its evaluation which is planned no later than 10 years after the entry into application of the revised rules.

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(2) Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: https://myintracomm.ec.europa.eu/corp/budget/financial-rules/budget-implementation/Pages/implementation-methods.aspx.

The centralised electronic system will allow for an efficient and continuous monitoring of operational activities. Most notably, it will harmonise the annual reporting requirements to the UN on legal trade and incidents related to drug precursors.

In addition, the Commission and to some extent EUDA will continuously monitor the application of the rules and the developments in precursor trade that may warrant an adaptation of the scope of the measures.

2.2. Management and control system(s)

2.2.1. Justification of the budget implementation method(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

The Regulation establishes new substantive requirements with regard to controlling the licit trade of drug precursors while ensuring fair competition among market actors in the internal market.

These new rules require an improved digital system for monitoring and controlling the internal and external trade of drug precursors. The enforcement and successful implementation of the new Regulation is estimated to require an additional FTE in the European Drugs Agency (EUDA) that will be financed under the contribution agreement between DG TAXUD and EUDA up to and including 2030

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

The risks associated to the financial transactions implementing the central electronic system are limited.

The specifications, development and operations of the central electronic system are implemented using existing framework contracts and/or via co-delegation to other Commission services.

GROW: N/A

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio between the control costs and the value of the related funds managed), and assessment of the expected levels of risk of error (at payment & at closure)

The costs of controls are negligible compared to the appropriations for the development of the IT tool itself

GROW: N/A

2.3. Measures to prevent fraud and irregularities

The measures implemented by the Commission will be subject to the ex-ante and ex-post controls in accordance with the Financial Regulation. Contracts and agreements financing the implementation of this Regulation will expressly entitle the Commission, including OLAF and the Court of Auditors to conduct audits, on the spot checks and inspections.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff. (3)	from EFTA countries (4)	from candidate countries and potential candidates (5)	from other third countries	other assigned revenue
5	121003	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO
	[XX.YY.YY.YY]	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO
	[XX.YY.YY.YY]	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO

New budget lines requested

(3) Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

(4) EFTA: European Free Trade Association.

(5) Candidate countries and, where applicable, potential candidates from the Western Balkans.

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./non-diff.	from EFTA countries	from candidate countries and potential candidates	from other third countries	other assigned revenue
	[XX.YY.YY.YY]	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO
	[XX.YY.YY.YY]	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO
	[XX.YY.YY.YY]	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

☐ The proposal/initiative does not require the use of operational appropriations

☐ The proposal/initiative requires the use of operational appropriations, as explained below

☐ The amounts indicated are strictly indicative, pending the final outcome of the MFF negotiations 2028-2034.

3.2.1.1. Appropriations from voted budget

EUR million (to three decimal places)

Heading of multiannual financial framework			Number					
DG: GROW			Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	**TOTAL MFF**
Operational appropriations								
Budget line	Commitments	(1a)	0.550	0.400	0.070	0.050	0.000	**1.070**
	Payments	(2a)	0.165	0.505	0.300	0.065	0.035	**1.070**
Budget line	Commitments	(1b)						**0.000**
	Payments	(2b)						**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes [6]								
Budget line		(3)						**0.000**
TOTAL appropriations for DG GROW	Commitments	=1a+1b+3	**0.550**	**0.400**	**0.070**	**0.050**		**1.070**
	Payments	=2a+2b+3	**0.165**	**0.505**	**0.300**	**0.065**	0.035	**1.070**

[6] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

DG:TAXUD			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line E.03050100	Commitments	(1a)					
	Payments	(2a)					
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes [7]							
Budget line E.03050100		(3)					
TOTAL appropriations for DGTAXUD	Commitments	=1a+1b+3	**0.000**	**0.000**			
	Payments	=2a+2b+3	**0.000**	**0.000**			

DG:TAXUD	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year 2032	Year 2033	Year 2034	**TOTAL MFF 2028-2034**

[7] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

Operational appropriations										
Budget line E.03050100	Commitments	(1a)	1.125	1.727	4.492	4.056	4.986	4.800	2.165	**23.351**
	Payments	(2a)	0.768	1.271	2.989	3.721	4.608	4.707	3.52	**21.584**
Budget line	Commitments	(1b)								**0.000**
	Payments	(2b)								**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes [8]										
Budget line E.03050100		(3)	0.107	0.109	0.112	0.114	0.116	0.118	0.121	**0.797**
TOTAL appropriations for DGTAXUD	Commitments	=1a+1b+3	**1.232**	**1.836**	**4.604**	**4.170**	**5.102**	**4.918**	**2.286**	**24.148**
	Payments	=2a+2b+3	0.875	1.38	3.101	3.835	4.724	4.825	3.641	22.381

	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	**Year 2034**	**TOTAL MFF 2028-**

[8] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

										2034
TOTAL operational appropriations (all operational headings)	Commitments	(4)	1.782	2.236	4.674	4.22	5.102	4.918	2.286	**25.218**
	Payments	(5)	1.04	1.885	3.401	3.9	4.759	4.825	3.641	23.451
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)	0.000	0.000	0.000	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations Under Heading 1 of the multiannual financial framework (Reference amount)	Commitments	=4+6	1.782	2.236	4.674	4.22	5.102	4.918	2.286	25.218
	Payments	=5+6	**1.04**	1.885	3.401	3.9	4.759	4.825	3.641	23.451

EUR million (to three decimal places)

			Year 2024	**Year 2025**	**Year 2026**	**Year 2027**	**TOTAL MFF 2021-2027**
TOTAL operational appropriations	Commitments	(4)					
	Payments	(5)					

TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)						
TOTAL appropriations under HEADING1 to 6 of the multiannual financial framework	Commitments	=4+6						
	Payments	=5+6						

			Year 2028	**Year 2029**	**Year 2030**	**Year 2031**	**Year 2032**	**Year 2033**	**Year 2034**	**TOTAL MFF 2028-2034**
TOTAL operational appropriations (all operational headings)	Commitments	(4)	1.782	2.236	4.674	4.22	5.102	4.918	2.286	**25.218**
	Payments	(5)	1.04	1.885	3.401	3.9	4.759	4.825	3.641	23.451
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)								
TOTAL appropriations Under Heading 1 to 6 of the multiannual financial framework (Reference amount)	Commitments	=4+6	**1.782**	**2.236**	**4.674**	**4.22**	**5.102**	**4.918**	**2.286**	**25.218**
	Payments	=5+6	1.04	1.885	3.401	3.9	4.759	4.825	3.641	23.451

Heading of multiannual financial framework		**7**		‘Administrative expenditure’ [10]		
DG: <.GROW.....>		Year **202**8	Year **2029**	Year **20**30	Year **20**31	**TOTAL MFF**
Human resources		0.063	0.063	0.063	0.063	**0.252**
Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <.....>GROW	Appropriations	**0.063**	**0.063**	**0.063**	**0.063**	**0.252**
DG: <.TAXUD.....>		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Human resources		0.000	0.000			
Other administrative expenditure		0.000	0.000	0.000	0.000	0.000
TOTAL DG TAXUD	Appropriations	**0.000**	**0.000**			
DG: <.TAXUD.....>		**Year 2028**	**Year 2029**	**Year 2030**	**Year 2031**	**TOTAL MFF 2028-2031**
Human resources						
Other administrative expenditure						

(10) The necessary appropriations should be determined using the annual average cost figures available on the appropriate BUDGpedia webpage.

TOTAL DG TAXUD					
DG: <.TAXUD.....>	**Year 2032**	**Year 2033**	**Year 2034**		**TOTAL MFF 2032-2034**
Human resources					
Other administrative expenditure					
TOTAL DG TAXUD					

DG GROW, DG		**Year 2024**	**Year 2025**	**Year 2026**	**Year 2027**	**Year 2028**	**Year 2029**	**Year 2030**	**Year 2031**	**Year 2032**	**Year 2033**	**Year 2034**	**TOTAL MFF**
TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)	**0.000**	**0.000**			**0.063**	**0.063**	**0.063**					**0.252**

EUR million (to three decimal places)

	Year 2024	**Year 2025**	**Year 2026**	**Year 2027**	**Year 2028**	**Year 2029**	**Year 2030**	**Year 2031**	**Year 2032**	**Year 2033**	**Year 2034**	**TOTAL MFF**

TOTAL appropriations under HEADINGS 1 to 7 of the multiannual financial framework	Commitments		**000**	**0.103**	**0.196**	**1.845**	**2.299**	**4.737**	**4.283**	**5.102**	**4.918**	**2.286**	**25.769**
	Payments		0.00	0.103	0.196	1.103	1.948	3.464	3.963	4.759	4.825	3.641	24.002

3.2.1.2.

EUDA: 12 10 03	Year **2028**	Year **2029**	Year **2030**	**TOTAL MFF 2028-2030**
Budget line: 12 10 03	0.087	0,173	0,173	0,433

For the current MFF, the need for the additional Contractual agent post for EUDA will be covered by a contribution agreement to be financed from the existing envelope of the Customs Programme.

For the next MFF the funding for the temporary agent as of 2028 until 2030 will be covered by the amounts in the EU Facility otherwise foreseen to fund actions in the domain of Home Affairs.

3.2.1.3. Appropriations from external assigned revenues

EUR million (to three decimal places)

Heading of multiannual financial framework	Number				
DG: <.....>	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**

Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes [11]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <.....>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
DG: <.....>			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitm	(1a)					**0.000**

(11) Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

	ents						
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes [12]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <.....>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Heading of multiannual financial framework		Number					
DG: <.....>			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**

(12) Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes [13]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <.....>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
DG: <.....>			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitm	(1a)					**0.000**

[13] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

	ents						
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[14]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <.....>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
TOTAL operational	Commitm	(4)	0.000	0.000	0.000	0.000	**0.000**

(14) Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

appropriations	ents						
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations under HEADING <....> of the multiannual financial framework	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Heading of multiannual financial framework		**7**			‘Administrative expenditure’ (15)		

EUR million (to three decimal places)

DG: <.....>		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Human resources		0.000	0.000	0.000	0.000	**0.000**
Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <.....>	Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

(15) The necessary appropriations should be determined using the annual average cost figures available on the appropriate BUDGpedia webpage.

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

EUR million (to three decimal places)

		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
TOTAL appropriations under HEADINGS 1 to 7 of the multiannual financial framework	Commitments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.2. Estimated output funded from operational appropriations (not to be completed for decentralised agencies)

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇓			Year **2024**		Year **2025**		Year **2026**		Year **2027**		2028-2034 Enter as many years as necessary to show the duration of the impact (see Section 1.6)								**TOTAL**			
OUTPUTS																						
Type	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No			Total Cost

SPECIFIC OBJECTIVE No 1 : [...]																						
- Output																						
- Output																						
- Output																						
Subtotal for specific objective No 1																						
SPECIFIC OBJECTIVE No 2 : [...]																						
- Output																						
Subtotal for specific objective No 2																						
TOTALS																						

3.2.3. Summary of estimated impact on administrative appropriations

☐ The proposal/initiative does not require the use of appropriations of an administrative nature

☐ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

3.2.3.1. Appropriations from voted budget

VOTED APPROPRIATIONS	Year 2024	Year 2025	Year 2026	Year 2027	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF
HEADING 7												
Human resources	0.000	0.000	0.103	0.301	0.374	0.177	0.181	0.185	0.116	0.118	0.121	1.676
Other administrative expenditure	0.000	0.000	0.000	0.000								**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.103**	**0.301**	**0.374**	**0.177**	**0.181**	**0.185**	**0.116**	**0.118**	**0.121**	**1.676**
Outside HEADING 7												
Human resources	0.000	0.000	0.000	0.000								**0.000**
Other expenditure of an administrative nature	0.000	0.000	0.000	0.000								**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**								**0.000**
TOTAL	**0.0**	**0.000**	**0.103**	**0.30**	**0.37**	**0.17**	**0.181**	**0.18**	**0.116**	**0.11**	**0.12**	**1.676**

				1	**4**	**7**		**5**		**8**	**1**	

3.2.3.2. Appropriations from external assigned revenues

EXTERNAL ASSIGNED REVENUES	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
HEADING 7					
Human resources	0.000	0.000	0.000	0.000	**0.000**
Other administrative expenditure	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Outside HEADING 7					
Human resources	0.000	0.000	0.000	0.000	**0.000**
Other expenditure of an administrative nature	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.3.3. Total appropriations

TOTAL VOTED APPROPRIATIONS + EXTERNAL ASSIGNED	**Year 2024**	**Year 2025**	**Year 2026**	**Year 2027**	**Year 2028**	**Year 2029**	**Year 2030**	**Year 2031**	**Year 2032**	**Year 2033**	**Year 2034**	**TOTAL MFF 2021-2027**

REVENUES												
HEADING 7												
Human resources	0.000	0.000	0.103	0.301	0.374	0.177	0.181	0.185	0.116	0.118	0.121	1.676
Other administrative expenditure												
Subtotal HEADING 7	**0.000**	**0.000**	**0.103**	**0.301**	**0.374**	**0.177**	**0.181**	**0.185**	**0.116**	**0.118**	**0.121**	**1.676**
Outside HEADING 7												
Human resources	0.000	0.000	0.000	0.000								0.000
Other expenditure of an administrative nature	0.000	0.000	0.000	0.000								0.000
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**								**0.000**
TOTAL	**0.0**	**0.000**	**0.103**	**0.301**	**0.374**	**0.177**	**0.181**	**0.185**	**0.116**	**0.118**	**0.121**	**1.676**

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together, if necessary, with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

3.2.4. Estimated requirements of human resources

☐ The proposal/initiative does not require the use of human resources

☑ The proposal/initiative requires the use of human resources, as explained below

3.2.4.1. Financed from voted budget

Estimate to be expressed in full-time equivalent units (FTEs) [16]

VOTED APPROPRIATIONS	Year **2024**	Year **2025**	Year **2026**	Year **2027**
Establishment plan posts (officials and temporary staff)				
20 01 02 01[3] (Headquarters and Commission's Representation Offices)	0	0	0	0
20 01 02 03 (EU Delegations)	0	0	0	0
01 01 01 01 (Indirect research)	0	0	0	0
01 01 01 11 (Direct research)	0	0	0	0
Other budget lines (specify)	0	0	0	0
External staff (in FTEs)				
20 02 01 (AC, END from the 'global envelope')	0	0		
20 02 03 (AC, AL, END and JPD in the EU Delegations)	0	0	0	0

(16) Please specify below the table how many FTEs within the number indicated are already assigned to the management of the action and/or can be redeployed within your DG and what are your net needs.

3 Starting from 2028 and up to 2031, it is to be noted that there are 0.3 establishment plan posts

Admin. support line [XX.01.YY.YY]	- at Headquarters	0	0	0	0
	- in EU Delegations	0	0	0	0
01 01 01 02 (AC, END - Indirect research)		0	0	0	0
01 01 01 12 (AC, END - Direct research)		0	0	0	0
Other budget lines (specify) - Heading 7		0	0	0	0
Other budget lines (specify) - Outside Heading 7		0	0	0	0
TOTAL		**0**			

3.2.4.2. Financed from external assigned revenues

EXTERNAL ASSIGNED REVENUES	Year **2024**	Year **2025**	Year **2026**	Year **2027**
Establishment plan posts (officials and temporary staff)				
20 01 02 01 (Headquarters and Commission's Representation Offices)	0	0	0	0
20 01 02 03 (EU Delegations)	0	0	0	0
01 01 01 01 (Indirect research)	0	0	0	0
01 01 01 11 (Direct research)	0	0	0	0
Other budget lines (specify)	0	0	0	0
External staff (in full time equivalent units)				

20 02 01 (AC, END from the global envelope)		0	0	0	0
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0
Admin. support line [XX.01.YY.YY]	- at Headquarters	0	0	0	0
	- in EU Delegations	0	0	0	0
01 01 01 02 (AC, END - Indirect research)		0	0	0	0
01 01 01 12 (AC, END - Direct research)		0	0	0	0
Other budget lines (specify) - Heading 7		0	0	0	0
Other budget lines (specify) - Outside Heading 7		0	0	0	0
TOTAL		**0**	**0**	**0**	**0**

3.2.4.3. Total requirements of human resources

TOTAL VOTED APPROPRIATIONS + EXTERNAL ASSIGNED REVENUES	Year **2024**	Year **2025**	Year **2026**	Year **2027**
Establishment plan posts (officials and temporary staff)				
20 01 02 01 (Headquarters and Commission's Representation Offices)	0	0	0	0
20 01 02 03 (EU Delegations)	0	0	0	0
01 01 01 01 (Indirect research)	0	0	0	0

01 01 01 11 (Direct research)		0	0	0	0
Other budget lines (specify)		0	0	0	0
External staff (in full time equivalent units)					
20 02 01 (AC, END from the global envelope)		0	0		
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0
Admin. support line [XX.01.YY.YY]	- at Headquarters	0	0	0	0
	- in EU Delegations	0	0	0	0
01 01 01 02 (AC, END - Indirect research)		0	0	0	0
01 01 01 12 (AC, END - Direct research)		0	0	0	0
Other budget lines (specify) - Heading 7		0	0	0	0
Other budget lines (specify) - Outside Heading 7		0	0	0	0
TOTAL		**0**	0		

The staff required to implement the proposal (in FTEs):

	To be covered by current staff available in the Commission services	**Exceptional additional staff***		
		To be financed	**To be financed**	**To be financed**

		under Heading 7 or Research	from BA line	from fees
Establishment plan posts	0.3		N/A	
External staff (CA, SNEs, INT)				

Description of tasks to be carried out by:

Officials and temporary staff	GROW: Plan, organize, and oversee IT project to ensure timely and budget-driven completion, managing resources, risks, and stakeholders to deliver system according to requirements.
External staff	

3.2.5. Overview of estimated impact on digital technology-related investments

Compulsory: the best estimate of the digital technology-related investments entailed by the proposal/initiative should be included in the table below.

Exceptionally, when required for the implementation of the proposal/initiative, the appropriations under Heading 7 should be presented in the designated line.

The appropriations under Headings 1-6 should be reflected as "Policy IT expenditure on operational programmes". This expenditure refers to the operational budget to be used to re-use/ buy/ develop IT platforms/ tools directly linked to the implementation of the initiative and their associated investments (e.g. licences, studies, data storage etc). The information provided in this table should be consistent with details presented under Section 4 "Digital dimensions".

TOTAL Digital and IT appropriations	Year 2024	Year 2025	Year 2026	Year 2027	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2021-2034

HEADING 7												
IT expenditure (corporate)	0.000	0.000										
Subtotal HEADING 7	**0.000**	**0.000**										
Outside HEADING 7												
Policy IT expenditure on operational programmes	0.000	0.000	0.103	0.196	**2.692**	**2.236**	**4.674**	**4.22**	**5.102**	**4.918**	**2.286**	**26.427**
Subtotal outside HEADING 7	**0.000**	**0.000**	0.103	0.334	**2. -966**	**2.508**	**4.948**	**4.22**	**5.102**	**4.918**	**2.286**	**27.385**
TOTAL	**0.000**	**0.000**	0.206	0.635	3.34	2.685	5.129	4.405	5.218	5.036	2.407	29.061

3.2.6. Compatibility with the current multiannual financial framework

The proposal/initiative:

☑ can be fully financed through redeployment within the relevant heading of the multiannual financial framework (MFF).

☐ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation.

☐ requires a revision of the MFF.

3.2.7. Third-party contributions

The proposal/initiative:

☐ does not provide for co-financing by third parties

☐ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year **2024**	Year **2025**	Year **2026**	Year **2027**	Total
Specify the co-financing body					
TOTAL appropriations co-financed					

3.2.8. Estimated human resources and the use of appropriations required in a decentralised agency

Staff requirements (full-time equivalent units)

A contribution agreement will be signed between DG TAXUD and EUDA to finance 1 contract agent from 2027 till 2030 (in total EUR 297000) and also the operational expenses concerning the repository of drug precursors (EUR 182.000 for years 2027 and 2028).

EU budget contribution to EUDA will be increased by EUR 433000 to finance 1 establishment plan post (TA) from 2028 till 2030. The funding will need to be covered by a compensatory reduction of the programmed spending of applicable programme budget lines of DG HOME, and without prejudice to the future MFF Agreement."

Agency: EUDA	Year 2024	Year **2025**	Year **2026**	Year **2027**	MFF 2028-2030
Temporary agents (AD Grades)					1

Temporary agents (AST grades)					
Temporary agents (AD+AST) subtotal		0	0	0	1
Contract agents				1	1
Seconded national experts					
Contract agents and seconded national experts subtotal				1	1
TOTAL staff				1	2

Appropriations covered by the EU budget contribution and a contribution agreement[4] in EUR million (to three decimal places)

Agency: EUDA	Year 2026	Year **2027**	TOTAL 2021-2027	MFF 2028-2030
Title 1: Staff expenditure		0.047	0.047	0.729
Title 2: Infrastructure and operating expenditure				
Title 3: Operational expenditure		0.091	0.091	0.091
TOTAL of appropriations covered by the EU budget		0.138	0.138	0.820

Appropriations covered by fees, if applicable, in EUR million (to three decimal places)

[4] One CA (0.343) covered by the contribution agreement plus operational expenses concerning the repository of drug precursors (0.182) and one TA (0.433)

Agency: <.....>	Year 2026	Year 2027	TOTAL 2021-2027	MFF 2028-2034
Title 1: Staff expenditure				0.000
Title 2: Infrastructure and operating expenditure				0.000
Title 3: Operational expenditure				0.000
TOTAL of appropriations covered by fees			0.000	0.000

Appropriations covered by co-financing, if applicable, in EUR million (to three decimal places)

Agency: <.....>	Year 2027	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL 2028-2034**
Title 1: Staff expenditure									0.000
Title 2: Infrastructure and operating expenditure									0.000
Title 3: Operational expenditure									0.000
TOTAL of appropriations covered co-financing		0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

Overview/summary of human resources and appropriations (in EUR million) required by the proposal/initiative in a decentralised agency

Agency: EUDA	Year 2027	**TOTAL 2021 - 2027**	Year **2028**	Year **2029**	Year **2030**	**TOTAL 2028-2030**
Temporary agents (AD+AST)		0	1	1	1	1
Contract agents	1	1	1	1	1	1
Seconded national experts		0	0	0	0	-
Total staff		0	0	0	0	-
Appropriations covered by the EU budget from 2028 and a contribution agreement	0.047	0.04700	0.183	0.272	0.274	0.729
Appropriations covered by fees (if applicable)		0.000	0.000	0.000	0.000	0.000
Appropriations co-financed (if applicable)		0.000	0.000	0.000	0.000	0.000
TOTAL appropriations	0.047	0.047	0.183	0.272	0.274	0.729

3.3. Estimated impact on revenue

☐ The proposal/initiative has no financial impact on revenue.

☐ The proposal/initiative has the following financial impact:

☐ on own resources

☐ on other revenue

☐ please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative [17]			
		Year **2024**	Year **2025**	Year **2026**	Year **2027**
Article					

For assigned revenue, specify the budget expenditure line(s) affected.

[...]

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

[...]

4. DIGITAL DIMENSIONS

4.1. Requirements of digital relevance

The effects of simplification of the legal framework, digitisation of processes and streamlining of obligations should contribute to positive impacts related to Objective #2, the facilitation of trade (and competition). Processes should be more efficient, there are fewer obligations to comply with overall.

Where currently Regulation (EC) 273/2004 requires verification of customer declarations through, in practice, paper-based procedures (since stamped copies of declarations are required), this measure would ensure a digital solution for the verification of customers trading in drug precursors internally. The digital solution would be an off-the-shelf digital solution, which provides for secure electronic interactions across the EU between businesses and public authorities.

[17] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20% for collection costs.

The obligations would be significantly streamlined for operators, with negligible implications for control overall, and significant savings for both public authorities and economic operators. Obligations that can be digitalised become digital, and those that (due to a centrally - EU - developed and digital solution) can be automated, are removed for operators. The solution would need to have the necessary functions listed in the Table below, including the requirements for customer verification (i.e., it allows for mutually recognised digital signatures, exchanging, and storing of documentation, etc.)

The proposed requirements would be driven by a centralised system connected with customs IT solutions via EU CSW-CERTEX to allow cross-check and availability check of license and/or registration for import or export transaction and quantity management. As such, the most significant work to establish the digital solution would be borne by the European Commission. Economic operators and Competent authorities responsible for the registration of operators and issuance of licences will use the central solution. With the digital solution, the EU eLicensing central portal for licenses and registrations would be connected to the EU Customs Single Window Certificates Exchange System and would contain information on substances, validity, quantity and whether exemptions apply, meaning that the authorisation process could be automated. Customs authorities of Member States stand to implement and interconnect the central solution with their national export and import systems once the processes are digitised.

The requirements of digital relevance are listed in the table below:

Reference to the requirement	**Requirement description**	**Actor(s) affected or concerned by the requirement**	**High-level Processes**	**Categories**
R1: Article 35(2), point (a)(i)	Access to the digital solution for operators (legal entities) legally trading with DP and public authorities	Economic operators, online market places, competent authorities, Commission	Management of registries	Digital Public Service, Digital Solution, Data
R2: Article 35(2), points (a)(ii), (iii) and (iv)	Submission of licence application, registration or prior-notification by economic operators	Economic operators, competent authorities, Commission	Filing an application or notification	Digital Public Service. Data

R3:Article 35(2), point (a)(v)	Verification of operators	Economic operators	Identification, fraud prevention	Digital Public Service, Process
R4: Article 35(2), point (b)	Provision of information on suspicious transactions	Economic operators, online market places, competent national authorities	Fraud prevention	Digital Public Service, Data
R5: Article 25	Drug Precursors Information Repository	General Public, Economic operators, competent authorities, Commission, EUDA	Management of registries	Digital Solution, Data
R6: Article 25(3)	Tool of the repository to check if a specific substance is part of group scheduling	Economic operators, competent authorities, Commission	Information and guidance	Digital Solution
R7: Article 35(2), points (c)(i) and (ii)	Validity check of registration and prior notification, and issuing licences or rejecting prior notifications, registrations or licenses	Economic operators, competent authorities	Fraud prevention	Digital Public Service, Process

R8: Article 35(2), point (a)(vi)	Information obligations regarding import / exports, and intermediary activities	Third countries, economic operators, competent authorities	Reporting	Digital Public Service, Data
R9: Article 23(2) and (6)	Validity check of registration/prior notification/license in course of import and export transactions	Third countries, economic operators, competent authorities	Fraud prevention	Digital Public Service, Process
R10: Article 35(5)	Interoperability with UN system for Pre-export notification	Third countries, economic operators, competent authorities	Reporting	Digital Solution
R11: Article 35(2), point (c)(iii)	Reporting of seizures by competent authorities	competent authorities	Reporting	Process
R12: Article 35(2), point (d)	Reporting to the International Narcotic Control Board	Commission, competent authorities	Reporting	Process
R13: Article 35(4)	Interconnection to the EU Single Window Environment for	Customs authorities, Commission	The Commission shall interconnect the	Digital Public Service, Digital

	Customs		central electronic system with the EU Single Window Environment for Customs established by Regulation (EU) 2022/2399	Solution
R14: Article 35(5)	Interoperability with UN system for seizure reporting	Commission	The Commission could interconnect the central electronic system with the electronic system of the United Nations	Digital Solution
R15: 35(2)c	Reporting to demonstrate fulfilment of obligations upon a reasoned request of competent authority with an "ad hoc" frequency.	Economic operators, Competent authorities and Customs	Fraud prevention, reporting	Data
R16:	Verification of generated annual reports by competent authorities	Competent authorities and Commission	Reporting	Digital public Service,

				Data, Process

4.2. **Data**

High-level description of the data in scope and any related standards/specifications

Type of data	**Reference to the requirement(s)**	**Standard and/or specification (if applicable)**
R1: Article 35(2), point (a)(i)	Information about economic operators	
R2: Article 35(2), points (a)(ii), (iii) and (iv)	License application, registration or prior notification	
R4: Article 35(2), point (b)	Report on suspicious transactions	
R5: Article 25	Information about substances covered by Annex I, II and III, in particular a general description of the substance and its chemical properties; information on legitimate uses and trade; information on the substance in the illicit production of drugs.	
R8: Article 35(2), point (a)(vi)	Information from operators about quantities to be imported or exported	

Alignment with the European Data Strategy

Explain how the requirement(s) are aligned with the European Data Strategy

For all requirements data management within the system is aligned with the European Data Strategy and its various aspects, ensuring following principles:

Digital by default:

All processes will be fully digitised.

Security and privacy:

As personal information will be stored in the central data base, compliance with the data protection legal acts is a must. Ownership of information remains at any time at national level, while ensuring strong security of information. The information to which each user/system will get access will be based on a strict need-to-know policy.

Openness and transparency:

The availability of all data is foreseen for validity check of license, self-registration and prior notification by trade partners of operators. The information will be available on a need-to-know basis as users will be assigned access to the database based on the credential provided by trader to its trade partner (by using QR code or eWallet). Transparency, harmonisation, and cross-checks of licences/registration will be ensured by the centralised repository storing the related information accessible to the authorities involved in the process.

Alignment with the EU Customs Data Model

The interaction with customs systems will be ensured by the compliance with the EU Customs Data Model (EUCDM). The data in scope and content is information related to the export and import of the goods. It will be available in the Commission Implementing Act, the specification of data requirement of every data field relevant for external trade will be described in the Delegated Regulation. The EU Customs Data Model is fully aligned with European Data Strategy.

User-centric, data-driven, agile

The data exchange is organized around the registration and licenses and related documents for the purpose of cross-border collaboration.

Stakeholders of data

Stakeholders for data flows are as per the table in ch.4.1 (EU institutions, Member States, third countries, businesses, public authorities).The information will be exchanged also between the actors involved as indicated in the Table

Alignment with the once-only principle

Data flows

For each data flow, please fill the table below:

Type of data	Reference(s) to the requirement(s)	Actor who provides the data	Actor who receives the data	Trigger for the data exchange	Frequency (if applicable)
Personal data of responsible officers in charge of licenses, self-registration or prior notification	R1	Competent authorities, economic operators	Competent authorities, Commission	Once the IT system is operational	24/7
Data relevant for licenses, registrations and prior notifications of operators	R2, R3, R7, R9, R12, R15, R16	Economic operators	Competent authorities, Economic operators	Request of operator	24/7
Data on suspicious transactions	R4, R15	Economic operators	Competent authorities	Request of operator	24/7
Data on seizures	R11, R12	Comptetent authorities	Commission, Competent authorities	Request of operator	24/7
Data on precursor substances	R5, R6	EUDA	Competent authorities, eonomic operators, General Public, Commission	Once uploaded	24/7

Data on drug precursor, quantity and time.	R8, R10, R12, R13, R15, R16		Competent authorities, Customs, Commission	Request of competent authorities, Commission	

Pre-export notification	R10		Competent authorities, Customs, third countries		

4.3. Digital solutions

For each digital solution, please provide the reference to the requirement(s) of digital relevance concerning it, a description of the digital solution's mandated functionality, the body that will be responsible for it, and other relevant aspects such as reusability and accessibility. Finally, explain whether the digital solution intends to make use of AI technologies.

Digital solution	**Reference(s) to the requirement(s)**	**Main mandated functionalities**	**Responsible body**	**How is accessibility catered for?**	**How is reusability considered?**	**Use of AI technologies (if applicable)**
Licensing, registration and prior notification platform	R1, R2, R3, R7, R9, R12, R16	Submission of licence application, registration or prior notification by economic operators, Verification of operators, validity checks of licences, registrations and prior notifications, possibility to grant/revoke/suspend licenses, order operators	GROW		The system will be built based on the EU DP database or any other appropriate IT component (tbc by ITCB based on Business Case)	no

		to suspend or cease an activity covered by prior notifications and registrations, sending ad hoc information requests				
Interconnection with customs	R8, R9, R13	Information provision, validity checks for import and export,	TAXUD		The system will be built based on the EU DP database or any other appropriate IT component (tbc by ITBC based on business case)	no
Drug Precursors Information Repository	R5, R6	(List of precursor substances to be filled in by EUDA, translation tool for extended scheduling	EUDA		This could be part of existing EUDA tools	no
Interface with INCB	R10, R12, R14	Sending and receiving of pre-export notifications with third	The concrete materialisation of the solution will be assessed during the		The solution will be built based on the EU DP database or any other appropriate	no

		countries to/from UN/INCB solution via machine-to-machine interface to be built; Opening, reviewing, processing and responding (if necessary) to the pre-export notifications sent by third countries' authorities to customs authorities; Drafting and completion of Annual reporting and statistics based on the information in Licensing platform, seizures reported and QM calculator	upcoming business analysis. (TAXUD responsibility)		IT component (tbc by ITBC based on business case)	
Administrative cooperation	R4, R11, R15	Provide a platform for competent	GROW		This will be part of the internal market IT	no

		authorities and economic operators to report seizures and suspicious transactions. Request ad hoc information to operators			system	

For each digital solution, explain how the digital solution complies with the requirements and obligations of the EU cybersecurity framework, and other applicable digital policies and legislative enactments (such as eIDAS, Single Digital Gateway, etc.).

Digital and/or sectorial policy (when these are applicable)	**Explanation on how it aligns**
AI Act	n/a
EU Cybersecurity framework	The Commission shall ensure the security, integrity, authenticity, and confidentiality of the data collected and stored for the purpose of this Regulation. To be further detailed in the specifications.
eIDAS	Most likely to be used for customer verification
Single Digital Gateway and IMI	IMI cannot provide for the real-time interoperability with customs systems.
EU SWE-C Framework	The Commission in cooperation with Member States will compose technical and functional specifications for interconnection of the system with national customs systems. Member States shall ensure the implementation.

4.4. Interoperability assessment

High-level description of the digital public service(s) affected by the requirements

Digital public service or category of digital public services	Description	Reference(s) to the requirement(s)	Interoperable Europe Solution(s) (NOT APPLICABLE)	Other interoperability solution(s)
EU licensing, registration and prior notification platform, Verification of operators, administrative cooperation platform	Economic operators submit applications and competent authorities process them, operators holding a licence and those who submitted a prior notification are to check that the operators to which they are planning to supply the relevant substances have a licence or submitted a prior notification. Notification of suspicious transactions, seizures, request information from operators	Art. 35(2)	//	
Connection to Customs systems	Quantity management,	Art. 35(4) and Article 23(2) and (6)		Interconnection to the EU Single Window Environment for Customs

Impact of the requirement(s) as per digital public service on cross-border interoperability

Licensing, registration prior notification platform, customer verification and administrative cooperation platform

Assessment	Measure(s)	Potential remaining barriers (if applicable)
Alignment with existing	- EU DP database of DG GROW or	-

digital and sectorial policies	eLicencings system from DG SANTE, or DG TRADE (to be confirmed by ITCB based on future Business Case) - Customer verification will leverage the European Business Wallets to authenticate and identify economic operators and public sector bodies across borders, while ensuring interoperability. In addition, the use of the European Business Wallets can be extended to the exchange of credentials (e.g., eLicences and eCertificates) and to the streamlining of reporting obligations.	
Organisational measures for a smooth cross-border digital public services delivery	- Art. 4 Free Movement - Chapter 2, in particular obligations of operators - Chapter 4, cooperation with and tasks of national authorities	
Measures taken to ensure a shared understanding of the data	- A single centralised system will provide the interface for all drug precursor formalities	- Interoperability with customs systems will not be immediately available.
Use of commonly agreed open technical specifications and standards	- Art. 6 communication is to happen in a machine-readable open standard.	-

Impact of the requirement(s) as per digital public service on cross-border interoperability

Connection to Customs Systems

Assessment	Measure(s)	Potential remaining barriers (if applicable)
Alignment with existing digital and sectorial policies **Please list the applicable digital and sectorial policies identified**	Regulation (EU) 2022/2399	
Organisational measures for a smooth cross-border digital public services delivery **Please list the governance measures foreseen**	The solution will alter the way actors interact with one another; paper documents will be replaced by electronic documents or messages, happening at a faster pace. The solution will have a significant impact on the following stakeholders: • Economic operators involved in external trade in drug precursors, who apply for licences electronically via the new system. • EU Member States competent authorities who receive applications for and issue licences • EU countries' customs offices who control customs declarations of drug precursors and verify the relevant licences electronically. The European Commission, which is responsible for the development and maintenance of the system, ensuring its functionality and compliance. The EU	

	countries are responsible for connecting their national customs systems to the EU CSW-CERTEX, which in turn ensures connection to the central solution.	
Measures taken to ensure a shared understanding of the data **Please list such measures**	- Data management will prioritise usability, reliability, and security, and support agile updates to meet evolving legal and operational requirements. The system will be aligned with the EU Customs Data Model (EUCDM) to ensure full interoperability with customs IT systems and compliance with EU customs legislation. Data elements required for import and export procedures will be harmonised and incorporated into future amendments to implementing and delegated regulations related to external trade in drug precursors.	-
Use of commonly agreed open technical specifications and standards **Please list such measures**	- Interoperability with customs systems such as EU CSW-CERTEX and TARIC is foreseen.	-

Describe the digital public service(s) affected by the requirements

The solution needs to be consistent with the EU Customs Single Window Digital Framework Policy. Where relevant, national single window systems would be connected to the EU Customs Single Window Certificates Exchange System, which in turn would be connected to the EU web portal for EO drug precursor procedures. Interoperability with international IT solutions such as PEN online could be ensured by the elaboration of the necessary technical specifications and the compliance to them. A machine-to-machine interface for communication with third countries authorities would facilitate the cross-border collaboration and administrative cooperation. MSs could access and see the messages such as PEN notifications received from third countries' partners in a web-based interface.

In line with the recommendations of the F4F Platform, Member States are requested to report incidents once only and in real-time through the EU. To avoid a duplication of reporting requirements an IT solution that allows for an exchange with the current UN alert system (PICS) would be required . If possible , the platform should communicate with INCB's PICS to avoid 'double reporting' burden and ensure consistency in the data gathered at EU and international level. MS will have to upload the information in the EU system, and such system could transmit the information to PICS.

The digital solutions could ensure interoperability across domains, including between the EU DP solution and customs systems for trade formalities and the reporting requirements of the international control system (e.g. PEN online, Form D, etc.).

The Interoperable Europe solutions identified for (re)use:

-

Interoperability with MSs national customs IT solutions should be ensured in line with rules and agreements on personal data processing and control.

As regards the possible interoperability of the new system with the solutions of the INCB who is responsible for the building of IT application of United Nations the EU signed the UN convention with elements of international cooperation in the area of preventing diversion of drug precursors. If applicable, the UN therefore should ensure compliance of its systems to the GDPR rules and conditions of SLA agreements allowing EU authorities to perform the work without delay. The centralised solution will ensure that the issued and electronically submitted certificates are available to customs authorities for cross-checks 24/7 (classified as "Silver" CI), hence not depending on non-synchronised working hours. No remaining barriers to cross-border interoperability are detected at the moment.

Interoperability with other customs systems such as the TARIC, EORI, CRMS etc. is envisaged.

4.5. Measures to support digital implementation

High-level description of measures supporting digital implementation

Description of the measure	**Reference(s) to the requirement(s)**	**Commission role** (if applicable)	**Actors to be involved** (if applicable)	**Expected timeline** (if applicable)
The Commission shall adopt implementing acts establishing common technical specifications for the electronic system	Art. 35(7), Art. 37	Commission to adopt the act	Member States	18 months after entry into force of the basic act.
Committee procedure	Art. 35(7)	The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	The Commission; committee; Member States	18 months after entry into force into force of the basic act.

The list of business functionalities is at high level and purely indicative at this stage and will be fine-tuned in context of the business analysis and inception phases, supported in part by the COM IT governance (Business Case and Project Charter), and to be legally covered in the dedicated Implementing Act for the external and international dimensions of the initiative.

Depending on the decision of ITCB[5] on the alternatives for development of the solution and delivery model, The Commission will chose between outsourcing the work to an external contractor or developing in-house (e.g. by DG GROW/DG SANTE/DG Trade etc).

As a first activity related to the development of the DP Licencing 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. The Commission 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 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 partner countries.

- Extend the existing platforms used in the EU for the authentication, authorisation and connection of users from the international partners.

- 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 medicine and customs authorities.

[5] IT development and procurement strategy choices will be subject to pre-approval by the European Commission Information Technology and Cybersecurity Board.

- 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. After the adoption of the proposal by the Commission 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 could also negotiate and adopt agreements on bilateral arrangements with third parties such as UN/INCB on data exchange together with Annex on technical arrangements.